STEM CELL LABORATORY (STCL)

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STCL-QA-006
Stem Cell Laboratory Quality Management Plan
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1 INTRODUCTION

1.1 Purpose of the Quality Management Plan

The purpose of this procedure is to describe the process by which the Stem Cell Laboratory (STCL) ensures that it can consistently provide products and services that meet or exceed customer, accreditation and regulatory requirements, and operate with efficiency to maximize quality.

1.2 Purpose of the Clinical Quality Program

A Clinical Quality Program (CQP) was established that is committed to quality assurance (QA) and quality improvement (QI). The CQP facilitates the development, implementation, and maintenance of effective Quality Management System (QMS) and routinely reports to management on the performance of the quality program for the Stem Cell Laboratory (STCL).

2 QUALITY POLICIES

2.1 The STCL Program/Medical Directors, STCL personnel, and the CQP are committed to providing quality products and services and ensuring a consistent standard of quality and compliance.

2.2 STCL will maintain a QMS that meets applicable regulations, accreditation standards, standard operating procedures (SOPs), and guidance documents.

2.3 STCL will continually improve the effectiveness of their QMS through periodic management review using appropriate metrics, and identification and management of risks.

2.4 STCL will establish quality objectives and through periodic management review, will ensure suitability of objectives.

2.5 STCL will maintain education and ongoing training to facilitate employee awareness and understanding of the Quality Management Plan (QMP).

3 QUALITY OBJECTIVES

3.1 Assure high quality products and services are consistently available, and procedures are consistently executed.

3.2 Assure the safety of donors, recipients, and healthcare personnel.

3.3 Maintain compliance with SOPs, applicable regulations, and accreditation standards.

3.4 Continuous Quality Improvement.

3.5 Trained and qualified personnel perform delegated tasks.

3.6 Control of QMS procedures.

4 OVERVIEW OF THE ORGANIZATIONAL STRUCTURE AND RESPONSIBILITIES

4.1 Management

4.1.1 The STCL's overall quality assurance programs are under the direction of the Department of Clinical Laboratories and Duke Cancer Institute (DCI) Clinical Quality Program (CQP). CQP is committed to the development, implementation, and continual improvement of the STCL's QMP and is responsible for communicating the effectiveness of the QMP and the importance of regulatory compliance throughout the organization.

4.1.2 The laboratory is under the direction of Dr. Joanne Kurtzberg, director of the Pediatric Blood and Marrow Transplant Program (PBMT), and Dr. Nelson Chao, director of the Adult Blood and Marrow Transplant Program. Dr. Gwynn Long, MD, BMT director of Quality and Accreditation in the Adult Blood and Marrow Transplant Program, is also a technical consultant.

See ***OC-002*** *for Adult & Pediatric Blood and Marrow Transplant Program Organizational Charts*.

4.2 Program Medical Directors

4.2.1 The STCL program medical directors or designee will have authority and responsibility for ensuring that the Quality Management Program is effectively established and maintained. The program medical directors exercise control in all matters relating to regulatory compliance and direct operations and resource planning efforts for the program. The program medical directors ensure that quality policies and practices are incorporated into procedures, that all employees receive adequate training, and are responsible for the development and timely implementation of corrective and preventive actions (CAPAs).

4.3 Clinical Quality Program (CQP)

4.3.1 The CQP reporting to the Duke Cancer Institute (DCI) facilitates the development, implementation, and maintenance of an effective Quality Management System. The CQP 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 CQP are distinct and separate from manufacturing and other technical operations. The Clinical Quality Program (CQP) provides oversight related to the processing, cryopreservation, storage and distribution of the products prepared in the STCL. The CQP 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 committee.

See ***OC-013*** *for Adult & Pediatric Blood and Marrow Transplant CQP Organizational Charts*

4.4 STCL Personnel

4. 4.1 STCL personnel, including management, administrative, manufacturing, and support staff, are required to have the education, training, and experience to

enable each person to perform their assigned functions, consistent with their job description. To maintain highly qualified personnel, the STCL utilizes an inclusive training program which includes annual training on the QMP, current Good Manufacturing Practice (cGMP) training, and annual training on job specific procedures.

4.4.2 The STCL Manager reports quality assurance data, on a quarterly basis, to a joint Pediatric and Adult Blood and Marrow Transplant Programs Committee and submits data to the Department of Clinical Laboratories, as needed.

4.5 STCL Organizational Chart

See ***OC-007*** *for current Stem Cell Laboratory Organizational Chart*

5 DEFINITIONS AND CONCEPTS OF QUALITY

5.1 Quality

5.1.1 Products have established identity, strength, purity, potency, and other quality characteristics designed to ensure the required levels of safety and effectiveness. Achieving quality means achieving these characteristics for a product.

5.2 Quality Assurance (QA)

5.2.1 QA activities are not tied to the actual performance of a process. QA includes retrospective review and analysis of operational performance data to determine if the overall process is in a state of control and to detect shifts or trends that require attention. QA involves review and approval of all procedures, change control requests, and validations related to production and maintenance, review of associated records, auditing, and performing/evaluating trend analyses. QA provides information regarding levels of performance that can be used in setting priorities for process improvement.

5.3 Quality Control (QC)

5.3.1 The purpose of QC is to provide feedback to operational staff about the state of a process that is in progress. QC is performed to determine whether the product or service meets specifications. It tells staff whether to continue (everything is acceptable) or whether to stop until a problem has been resolved (something is found to be out of control). STCL is responsible for applying and documenting appropriate QC methods and ensuring that objective evidence of QC is generated.

5.4 Quality Improvement (QI)

5.4.1 QI is intended to attain higher levels of performance either by creating new or better features that add value or by removing existing deficiencies in the process, product, or service.

5.5 Risk Management

5.5.1 Quality risk management is a valuable component of an effective quality systems framework. Quality risk management can, for example, help

guide the setting of specifications and process parameters for manufacturing, assess and mitigate the risk of changing a process or specification, and determine the extent of investigations and corrective actions. Quality risk management is incorporated into the change control and deviation processes.

5.5.2 All errors and near-misses are reported through an online hospital-wide SRS documentation system. Follow up is done by the managers in the area involved with the error. Serious adverse events are reviewed by the principle investigator and are reported to the IRB per institutional requirements.

5.5.3 Any serious adverse event or accident is reported to Risk Management and follow up actions are determined based on the severity of the problem and reporting of event to the appropriate regulatory agency if required.

5.6 Quality System

5.6.1 Implementing a comprehensive quality system facilitates compliance with current cGMP regulations. A Quality System encompasses all activities necessary to assure the finished product meets its predetermined design specification. This includes assuring processes are controlled and adequate for their intended use, documentation is controlled and maintained, and equipment is calibrated, inspected, tested, etc.

6 SELECT QUALITY REGULATIONS

6.1 Regulations

6.1.1 Current Good Manufacturing Practice (cGMP) for Finished Pharmaceuticals - 21CFR211.22

(a) There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company. (b) Adequate laboratory facilities for the testing and approval (or rejection) of components, drug product containers, closures, packaging materials, in-process materials, and drug products shall be available to the quality control unit. (c) The quality control unit shall have the responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product.

6.1.2 Quality System Regulation - 21CFR820

Each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of this part.

6.1.3 Human Cells, Tissues, and Cellular and Tissue-Based Products - 21CFR1271.160

If you are an establishment that performs any step in the manufacture of human cells, tissues, and cellular and tissue-based products (HCT/Ps), you must establish and maintain a quality program intended to prevent the introduction, transmission, or spread of communicable diseases through the manufacture and use of HCT/Ps. The quality program must be appropriate for the specific HCT/Ps manufactured and the manufacturing steps performed. The quality program must address all core cGTP requirements listed in Sec. 1271.150(b).

7 QUALITY MANAGEMENT SYSTEMS

7.1 Personnel/Training

7.1.1 Training is an essential component of personnel competency and is a regulatory requirement. All personnel must have appropriate training to enable them to perform their assigned function(s). Job training will include specific duties of the job function, and relevant parts of cGMP, Good Laboratory Practice (cGLP), and Good Clinical Practice (cGCP), any hygienic practices relevant to the specific job duties, and any safety practices relevant to the specific job duties.

7.1.2 New employees are oriented to the STCL policies and procedures pertinent to their sections and are trained for their assigned job functions. (See *STCL-TRN-001 Training* procedure).

7.1.3 Job competency is assessed annually. (See *STCL-TRN-001 Training and STCL-TRN-001 FRM2 Competency Assessment Form*).

7.1.4 Employees are expected to participate in CME activities and to maintain licensure and accreditation as required.

7.1.5 Performance evaluation is discussed with employees at least annually.

7.1.6 Proficiency testing is performed on an ongoing basis to assess general performance of policies and procedures, personnel, equipment, reagents and supplies.

7.1.7 Each employee will participate in safety training programs as defined by their duties.

7.1.8 The CQP manages the documentation of SOP training within MasterControl and facilitates quality training including annual cGMP and Good Documentation Practices (GDP) to promote regulatory compliance. Technical and cGMP-based training is conducted and documented prior to personnel undertaking new tasks or duties. At minimum, biennial review of SOPs by the author/owner of the SOP is triggered within MasterControl. During system/process audits, CQP reviews training files to ensure duties are performed by qualified and trained staff and training records are current.

7.1.9 Task-oriented assessment of the competency of staff members to perform their assigned duties will be procedure-specific. Assessment of competency for tasks may include any, or all, of the following:

7.1.9.1 Monitoring the recording and reporting of routine operations and procedures.

7.1.9.2 Review of worksheets, quality control records, proficiency test results, and/or preventive maintenance results.

7.1.9.3 Assessment of a staff member's performance in the mock-up of a procedural discrepancy situation.

7.1.9.4 Assessment of problem solving skills (may include written testing, review of problem reports, procedure reviews etc.).

7.1.9.5 Direct observation of performance of procedure.

7.1.9.6 Direct observations of performance of instrument maintenance and function checks

7.1.9.7 Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples

7.1.9.8 Assessment of problem solving skills

7.1.10 A technologist will only handle/process **one cellular therapy product** (*ie. HPC, Apheresis, HPC, Marrow, HPC, Cord, etc*) in the biological safety cabinet at any given time. *(**NOTE**: This is specific for the processing section of the laboratory; HPCA and Flow Cytometry testing sections of the laboratory perform batch testing whenever practical*).

7.2 Facilities and Safety

7.2.1 The STCL maintains a safe work environment for employees in compliance with all applicable standards and regulations. (*See STCL-GEN-012 Safety*).

7.2.2 A primary objective of the STCL QMP is to ensure that all critical aspects of the facility and equipment are qualified. Central to this goal is the appropriate design, installation, operation, and monitoring of facilities and equipment.

7.2.3 The monitoring systems used by the STCL Processing Laboratory are REES and Duke's Building Automating System (BAS). Procedures describing the automated monitoring systems and defined temperatures, humidity, are established.

7.2.4 cGMP and cGTP regulations require that any facility used in the manufacture, processing, packaging, labeling, or storage of human cells, tissues, and cellular and tissue-based products must be maintained in a clean and sanitary condition. Processing is performed in a clean environment which is achieved by using aseptic technique for all product processing. To assist in obtaining the cleanest, most sanitary environment possible, daily, weekly, and monthly cleaning and decontamination procedures are defined for STCL Laboratory personnel and for the external, contracted cleaning service engaged in the cleaning

and decontamination of the STCL Laboratory Facility. Procedures are in place to minimize product cross contamination.

7.2.5 Contingency plans in the event of a local, national, or international disaster are established and describe the infrastructure and procedures to respond to these disasters in a timely manner salvaging as many products as possible.

7.3 Equipment, Supply and Specimen Management

7.3.1 Critical Supplies/services are identified and criteria for the quarantine acceptance, or rejection of supplies are established. Vendor qualification is performed on vendors of critical supplies/services to ensure STCL quality standards are maintained. (See *STCL-GEN-002 Supply Management* procedure for details)

7.3.2 Whenever possible reagents and supplies used for testing, processing, cryopreserving and thawing must meet appropriate FDA criteria (see CFR Title 21, Part 660). Licensed reagents (when available) must be used and in-date.

7.3.3 When a reagent/solution/supply is not covered by FDA criteria or when the licensed reagent is not available or is rare, unlicensed or expired, reagents may be used with proper documentation, quality control, and/or supervisor approval.

7.3.4 New reagents shall be dated and initialed upon opening and new expiration date noted (*if the expiration date is different then what is reflected on the container once it has been opened*).

7.3.5 The new bottle should also be tested for reactivity, if indicated, before being placed into use.

7.3.6 Control specimens shall be tested in the same manner as recipient samples.

7.3.7 Control results must be verified as acceptable before reporting test results.

7.3.8 Reagents/supplies that appear to be contaminated shall not be used for testing or processing.

7.3.9 Reagents/supplies shall be used as prescribed by the manufacturer whenever possible.

7.3.10 Components of a reagent “kit” shall be used only within that kit lot unless otherwise specified by the manufacturer.

7.3.11 Vendors should be selected based on their ability to provide equipment that meets these performance standards. Selection considerations might include equipment design, validation of intended use, training and service support, licensure, and the company’s commitment to quality.

7.3.12 The STCL qualifies each piece of critical equipment to ensure it performs as expected and maintains the operation of this equipment by adhering to necessary maintenance, calibration, and certification schedules. (See *STCL-EQUIP-008 Quality Control Systems for STCL* and *COMM-QA-*

044 Approaches to Validation and *STCL Quality Assurance Policy* for details).

7.3.13 Equipment should be used as procedures and manufacturer's directions dictate whenever possible.

7.3.14 Quality control and preventative maintenance shall be performed on all pieces of equipment as specified in procedures and/or checklists. These steps shall meet regulatory requirements and manufacturer's recommendations.

7.3.15 Thermometers or other temperature sensing devices shall be placed in each refrigerator, freezer, incubator, heat block, water bath, or other equipment used for testing or storage of HPC/T, reagents, or samples (*especially if monitored by the REES system in case it goes down*).

7.3.16 Specimens received in the Stem Cell Laboratory should be labeled appropriately according to SOPs. Blood specimens received in the STCL should be labeled to include: the patient's full name, history #, and date of birth. Refer to *COMM-PAS-003 Labeling Cellular Therapy Products*, *STCL-SOP-043 Receipt of Products in the Stem Cell Laboratory*, etc. for product-specific labeling requirements.

7.4 Documents/Procedures

7.4.1 All Controlled Documents (*SOP's, official logs and forms*) are maintained according to strict standards for format, version control, and storage. (See *COMM-QA-016 Procedure Management* for details regarding document control and Procedure Development for creating procedures.)

7.4.2 Before new or revised procedures are implemented, they must be validated and/or verified and staff must be trained (see *STCL-GEN-013 Procedure Verification for STCL*).

7.4.3 Procedures are reviewed annually by the Medical Director and Laboratory Manager and/or designees.

7.4.4 Procedures retired from use must be archived and retained.

7.4.5 To meet or exceed customer requirements, it is imperative that STCL capture customer feedback and initiate process improvement plans as warranted. Once systems are in place, there is a need for continuous improvement. The STCL monitors its activities to determine methods of improving them. Additionally, nonconforming events are considered opportunities to improve processes. (See *STCL-QA-007 Non-Conforming Products – Receipt, Processing, Distribution, and Disposition*).

7.4.6 Steps in operating procedures must be defined and monitored to ensure consistency in performance. This is inherent in all procedures utilized by the STCL.

7.5 Contracts

7.5.1 The establishment and maintenance of written agreements with third parties whose services impact the clinical care of the patient and/or donor are obtained per Duke University Medical Center Hospital policies and procedures.

7.6 Records

7.6.1 All donor and recipient records are considered confidential and will be protected per HIPPA regulations.

7.6.2 All records must 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, and corrected in GMP fashion of striking through the error with one line, and marking the date and initials of the person making the correction.

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

7.6.4 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 recipient identification and to detect significant changes during task performance.

7.6.5 Computer procedures incorporate entry verification steps prior to data acceptance to help assure entry accuracy.

7.6.6 Correction of results entered electronically in EPIC Beaker will be corrected using the "Correct a Verified Result" procedure used by Clinical Laboratories. Correction of results in EMMES or other LIS can be tracked by those who maintain each computer system.

7.6.7 Results that are corrected but NOT entered into the EPIC Beaker system, will be communicated to the clinical team, as deemed appropriate, via e-mail, phone call, text page, and/or corrected report. Corrected results will be available in the patient's laboratory file.

7.6.8 Test results and critical documents are reviewed as specified.

7.6.9 Significant abnormal results are reported to the appropriate attending physician. (See *STCL-EQUIP-011 Sterility Cultures Using the BacT/Alert Microbiology* System for reporting positive cultures, *STCL-SOP-028 Procedure for Thawing Umbilical Cord Blood Units Frozen in Two Compartment Bags Using Dextran-Albumin Solution* for problems with UCB transplants. See (FRM1) for infusion problems.

7.6.10 Procedures describe disposition of improperly labeled specimens. (See STCL-SOP-037 Unacceptable Specimen Log, *STCL-SOP-038 FRM2 Confirmation of Specimen Identification Form, STCL-SOP-043 Receipt of Products in the Stem Cell Laboratory)*

7.6.11 Records are stored and retained as per the policies of Duke University Medical Center and the Adult and Pediatric Blood and Marrow Transplant Programs. (See *COMM-PAS-002 Record Retention Schedule* for details.)

7.6.12 Records should be retrievable within a reasonable amount of time.

7.6.13 Data on the servers gets backed up regularly. There is a daily incremental backup (any files that are created or changed since the previous day) and a total backup each week. If the servers go down the inpatient and clinic teams will record their data on flow sheets and enter it into the database after the server is restored.

7.6.14 The Stem Cell Laboratory (STCL) uses Advantage EDC^{SM}, electronic data capture system, for electronic record management. The system is maintained by the EMMES Corporation and can be accessed from any computer connected to the Internet. The system allows participating users to submit validated data forms and receive immediate feedback using secure transmission technology.

7.7 Communication

7.7.1 The STCL is committed to establishing a high standard of communication between the laboratory, clinical teams, and services within Duke University Medical Center, our customers, and external agencies. All complaints are addressed in a timely manner and viewed as potential opportunities for improvement. Corrective actions are initiated as deemed appropriate following investigation by the laboratory manager and/or designees.

7.8 Disaster Plan

7.8.1 Unexpected natural, physical and man-made disasters which could affect the integrity of human cell products stored in the stem cell laboratory and cord blood bank can occur without warning. Contingency plans need to be in place to respond to these disasters in a timely fashion salvaging as many cell products as possible. Advanced planning for some types of disasters that might occur is possible. The *STCL-GEN-008 Stem Cell Laboratory Disaster Plan* outlines the steps to be taken if a disaster affecting the Stem Cell Laboratory were to occur.

7.8.2 In addition, the Stem Cell Lab and the Adult and Pediatric Blood and Marrow Transplant Programs participate formally in the National Marrow Donor Program Core Contingency Networks for nuclear disasters.

7.8.3 Some types of disasters can be anticipated and managed with advanced planning. Examples of these would be floods, power outages, water contamination, and other weather related events.

7.9 Assessment Schedule

7.9.1 Assessment of quality is essential. Participation in external and internal audits ensures that the quality system is meeting the stated requirements. Quality indicators must be identified and monitored for all operations and

actions must be taken when unacceptable performance is demonstrated. (See *COMM-QA-039 Quality Systems Unit Audit* for detailed procedure and internal assessments)

7.9.2 Parameters reviewed include engraftment, graft failure, product contamination, regimen related toxicity, deaths and survival. In addition, specific endpoints are identified in laboratory processing orders (*e.g. CD34 targets for PBPC collection*). The STCL reports quality parameters on a monthly or quarterly schedule, as indicated.

7.9.3 Per CAP requirement GEN 23584 interim self-inspections are performed by STCL.

7.10 Variances and Corrective Actions

7.10.1 The STCL is committed to capturing all incidents and analyzing the information to identify systematic problems, determine root causes, and implement suitable short term/long term corrective actions and report to regulatory agencies, as deemed necessary.

7.10.2 Variances and deviations noted in any of the elements listed above should immediately be called to a supervisor's attention and documented (See *COMM-QA-042 Deviations and Investigations, STCL-QA-007 Non-Conforming Products - Receipt, Processing, Distribution, and Disposition* and *APBMT-COMM-030 Recording and Reporting of Adverse Events* for adverse event reporting.

7.10.3 Corrective actions will be determined by the Laboratory Director(s), the Laboratory Manager, and/or the CQP.

7.10.4 For External Audits: the CQP and Medical Director or designee will accompany inspectors performing external audits and facilitate their inspection as well as attend inspection exit meetings. Other designated STCL staff may attend these audits / inspections as well.

7.11 Disaster

7.11.1 When a disaster occurs (*or is forecasted*), notify Laboratory and Program directors, STCL staff, Clinical Quality Program, etc.

7.11.2 Check to ensure that the safety and wellness of staff and occupants in the affection location is not compromised.

7.11.3 Assess the physical damage at the affected location(s).

7.11.4 Establish essential chains of communication so that updates can be relayed in a timely manner.

7.11.5 Perform assessments to determine whether or not phones, pagers, wireless communication devices, computers, fax machines, and local, regional, national, and international networks are working properly.

7.11.6 Activate Core Contingency Communication phone, if indicated. (*See Government Emergency Telecommunications Service Calling Card Memorandum of Understanding in Core Contingency notebook*).

7.11.7 Assess whether the disaster is a threat to the Stem Cell Laboratory on a local, regional, and/or national level. This assessment will help determine if requests for support need to be made to Duke University Medical Center or if requests for assistance need to be made on a national and/or international level.

7.11.8 Access and evaluate the type of disaster to determine if it is natural (*e.g. floods, hurricanes, tornados, ice storms*), man-made (*e.g. explosion, fire*), nuclear, biological (*e.g. anthrax*), etc.

7.11.9 Access the appropriate networks available at DUMC, NIH, HHS, and/or the NMDP so that disaster teams can be activated, if appropriate.

7.11.10 For specific disasters that threaten the integrity of the cellular products housed in or by the Stem Cell Laboratory,

7.11.11 Check the integrity of the freezers housing cellular products.

7.11.12 Check the source of LN2 to ensure that the bulk tanks have not been compromised.

7.11.13 Check levels of LN2 in those freezers housing cellular products.

7.11.14 Check temperatures of ultra-low mechanical (electric) freezers.

7.11.15 Check the function of alarm systems to ensure they are still functional.

7.11.16 Check the back-up power source (generator) to ensure that it is functional.

7.11.17 If damage to any TG dewar has occurred, contact TG or designee to report the issue and activate the Dewar Replacement Contract.

7.11.18 Communicate with Duke's Refrigeration Department and/or Barlow Scientific to coordinate getting equipment loaners in place, as needed.

7.11.19 Communicate with the Stem Cell Processing Laboratory at UNC-CH (966-7820) or the UNC Blood Bank (966-4011), if needed, to discuss sharing of space and/or equipment.

7.11.20 If UCB units must be provided to other areas experiencing nuclear threats, communicate directly with the NMDP (or other designated agency) so selection and distribution of donor units can be determined.

8 RELATED DOCUMENTS/FORMS

8.1 STCL-SOP-037 Unacceptable Specimen Log

8.2 STCL-SOP-038 FRM2 Confirmation of Specimen Identification Form

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

8.3 STCL-FORM-030 Cap Survey Review Form

8.4 STCL-FORM-031 SCT Proficiency Survey Review Form

8.5 STCL-GEN-002 Supply Management

8.6 COMM-QA-016 Procedure Management

8.9 COMM-QA-057 Procedure Development

8.10 STCL-GEN-013 Procedure Verification for STCL

8.11 STCL-GEN-012 Safety

8.12 COMM-QA-042 Deviations and Investigations

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

8.14 COMM-QA-Approaches to Validation

8.15 COMM-QA-039 Quality Systems Unit Audit

8.16 COMM-PAS-004 Change Control

8.17 COMM-QA-059 Requesting Variances

8.18 STCL-EQUIP-011 Sterility Cultures Using the Bact/Alert Microbiology System

8.19 COMM-PAS-002 Record Retention Schedule

8.20 STCL-GEN-008 Stem Cell Laboratory Disaster Plan

8.21 STCL-TRN-001 Training in Stem Cell Laboratory

8.22 STCL-TRN-001 FRM 2 Competency Assessment Form

8.23 STCL-EQUIP-008 Quality Control Systems for the STCL

8.24 OC-002 Adult Cell Therapy and Transplant Program, Pediatric Blood and Marrow Transplant Program

8.25 OC-007 Stem Cell Laboratory Organizational Chart

8.26 OC-013 APBMT CQP Organizational Chart

9 REFERENCES

9.1 FDA: Code of Federal Regulations, Title 21.

9.2 AABB: Standards for Blood Banks and Transfusion Services; Accreditation Requirements Manual.

9.3 CAP: Transfusion Medicine Inspection Booklet.

9.4 JCAHO: Accreditation Manual for Hospitals.

9.5 CLIA: Clinical Laboratory Improvement Act, 1988, Title 42, Part 493.

9.6 FACT: Standards, Current Edition

9.7 Physician Training for Transplant Program Director and Attending Physicians Checklist

10 REVISION HISTORY

Revision No.	Author	Description of Change(s)
17	M. Ritt	• Removed reference to Quality Systems Unit (QSU) throughout the document and replaced with Clinical Quality Program (CQP) • Added reference to OC-013 APBMT CQP Organizational Chart

Signature Manifest

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