



STEM CELL LABORATORY (STCL)



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Records Management

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STCL-GEN-015

RECORDS MANAGEMENT

1 PURPOSE

- 1.1 The purpose of this procedure is to describe the necessary components of the records management system for the Stem Cell Laboratory (STCL).

2 INTRODUCTION

- 2.1 Programs shall establish, document and maintain a records management system that encompasses the requirements listed in this procedure. The Stem Cell Laboratory uses the paper system as the primary method of documentation for the program.

3 SCOPE AND RESPONSIBILITIES

- 3.1 This procedure describes records management including record retention per *COMM-PAS-002 Records Retention Schedule* for the Stem Cell Laboratory.
- 3.2 The Program/Medical Director, Supervisor/Managers, applicable Program personnel, and CQP are responsible for ensuring the requirements of this procedure are successfully met.

4 DEFINITIONS/ACRONYMS

- 4.1 CQP Clinical Quality Program
- 4.2 NMDP National Marrow Donor Program
- 4.3 STCL Stem Cell Laboratory
- 4.4 N/A Not Applicable
- 4.5 LIS Laboratory Information System

5 MATERIALS

- 5.1 N/A

6 EQUIPMENT

- 6.1 File Cabinets
- 6.2 Shred Boxes
- 6.3 Computer

7 SAFETY

- 7.1 N/A

8 PROCEDURE

- 8.1 Documentation
 - 8.1.1 Records shall be legible and indelible.

- 8.1.2 Records shall be in blue or black indelible ink.
- 8.1.3 Records are reviewed for completeness on a schedule defined in applicable procedures. See *STCL-QA-005 Review of Processing Records* and associated forms.
- 8.1.4 Records shall be made concurrently with each step of collection, processing, testing, storage, and disposition of every cell therapy component, in such a way that all steps may be accurately traced.
- 8.1.5 Records shall identify the person immediately responsible for each step, the dates (and time if applicable) of various entries and be as detailed as necessary to provide a complete history of the work performed, and to relate records to a specific cellular therapy product.
- 8.1.6 All statements must be written clearly and accurately.
- 8.1.7 Signatures, whether electronic or hand-written, represent a legal statement about the accuracy of the completed activity (ies).
- 8.1.8 Appropriate records shall be available from which to determine the lot numbers and manufacturer of supplies and reagents used for the collection and processing of specific components.

8.2 Corrections

- 8.2.1 In a blue or black ink pen, staff shall cross through the error with a single line. Do not use pencil, felt tip, gel tip (water soluble) pens.
- 8.2.2 The line must not obliterate the original entry; it must be legible. Staff must not use correction fluid or scribble to obscure the original entry
- 8.2.3 Staff must legibly write the correct information as close as possible to the original entry. Initial, date and provide rationale if necessary.
- 8.2.4 Deleting incorrect information where there is no correction; staff should draw a line through, then initial, date and provide rationale.
- 8.2.5 Recreated records shall be clearly designated as “duplicate” or “recreation”, shall be dated and initialed, and original attached if available.
- 8.2.6 When reviewing documents completed by non-program personnel e.g., a patient/donor, and clarification is required, add date, initials and explanation as necessary to clarify data entry.

8.3 General Storage Requirements

- 8.3.1 Records shall be maintained in such a way as to assure their preservation and protection from accidental or unauthorized modification.
- 8.3.2 Records shall be readily retrievable.
- 8.3.3 Records containing confidential information shall be maintained in locked storage.

8.4 Archival Requirements

8.4.1 Archived records must be retrievable.

8.5 Electronic Records

8.5.1 If a computer record-keeping system is used, there shall be a system to ensure the authenticity, integrity, and confidentiality of all records.

8.5.2 There shall be a protection of the records to enable their accurate and ready retrieval throughout the period of record retention.

8.5.3 There shall be an alternative system that ensures continuous operation, in the event that computerized data are not available.

8.5.4 There shall be established written procedures for record entry, verification, and revision. A system shall be established for display of data before final acceptance.

8.5.4.1 The Stem Cell Laboratory (STCL) uses Advantage EDCSM electronic data capture system, for electronic record management. The system is maintained by the EMMES Corporation and can be accessed from any computer via the Internet. The system allows participating users to submit validated data forms and receive immediate feedback using secure transmission technology. See *STCL-GEN-015 JA1 EMMES System Advantage EDCSM*.

8.5.4.2 The Stem Cell Laboratory (STCL) uses the Laboratory Information System (LIS) to enter designated laboratory test results so the information is accessible by the medical team via other electronic systems (i.e. EPIC, Beaker, or equivalent, etc.). See *STCL-SOP-058 Laboratory Test Ordering STCL-SOP-058 JA1 Ordering STCL Tests in Epic Beaker – Open Encounter, STCL-SOP-058 JA2 Ordering STCL Test in EPIC Beaker - Closed Encounter, STCL-SOP-058 JA3 Entering Test Results in EPIC Beaker* and *STCL-SOP-058 JA4 Maestro Care Quick Start Guide Beaker Clinical Pathology*.

8.5.4.3 The Stem Cell Laboratory (STCL) uses MasterControl, which is a web-based, password protected, document management system, used to control all documents (SOP's, official logs, job aides, and forms). (See SOP: *DCO-SOP-004 Document Control Procedures for MasterControl*). The system is maintained by the Quality Systems Unit.

8.5.4.4 The Stem Cell Laboratory (STCL) uses the Stem Cell Laboratory Access Database to generate Cryopreservation Reports and Infusion Reports specifically for patients being treated by the Adult Blood & Marrow Transplant Program since this information is required as part of the patient's admission packet. This database is maintained by the ABMT Program senior analyst (*or designee*).

- 8.5.5 There shall be the ability to generate true copies of the records in both paper and computer form, suitable for inspection and review.
- 8.6 Record Requirements / Retention - Records are maintained indefinitely unless otherwise specified within this document or other document.
 - 8.6.1 Donor records are retained indefinitely.
 - 8.6.2 Allogeneic records require recipient information sufficient to permit tracking.
 - 8.6.3 Donor found unsuitable by the collection/processing service.
 - 8.6.3.1 Reason for deferral.
 - 8.6.3.2 Record of donor notification of deferral, *if applicable*.
 - 8.6.3.3 Record of products from unacceptable donors.
 - 8.6.4 Facility Records
 - 8.6.4.1 Identifying information for all facilities providing donor selection information, product collection, processing or testing.
 - 8.6.4.2 Identifying information for all facilities, providing recipient selection information, compatibility testing, record keeping, and treatment for disease or transplantation.
 - 8.6.5 Processing Records
 - 8.6.5.1 Physician authorized for collection, *if required*.
 - 8.6.5.2 Product name, unique identifier, preparation volume and additives, date of collection and date of processing.
 - 8.6.6 Details of product processing, including the following:
 - 8.6.6.1 Measurements of established collection and processing parameters.
 - 8.6.6.2 Manipulations other than minimal.
 - 8.6.6.3 Name, lot number, and expiration date of all reagents and supplies used during processing.
 - 8.6.6.4 Labeling, including initials of personnel performing any container transfer.
 - 8.6.6.5 Verification of the accuracy of the final container label before issue.
 - 8.6.6.6 Name and address of the processing facility.
 - 8.6.6.7 Label reconciliation per STCL-GEN-015 JA3 Disposition of Labels and Barcodes
 - 8.6.7 Storage and Distribution Records
 - 8.6.7.1 Reissuance, including temperature records.
 - 8.6.7.2 Final disposition of each product.

- 8.6.7.3 Total inventory of stored products at any given time.
- 8.6.7.4 Visual inspection of liquid components during storage and immediately before infusion.
- 8.6.7.5 Storage temperature. See *STCL-EQUIP-021 Temperature and Environmental Monitoring Systems for Stem Cell Laboratory, STCL-EQUIP-021 JA1 Rees Scientific – Centron Presidio User Guide, STCL-EQUIP-021 JA2 Duke University Users Guide – Building Automation Systems, STCL-EQUIP-021 JA3 Duke University Users Guide – Hospital Refrigeration, STCL-EQUIP-021 JA4 Quick Guide to Responding to REES alarms*. The following records related to the administering of cellular therapy products are retained indefinitely – Autologous recipient records:
 - 8.6.7.6 Patient identification and diagnosis.
 - 8.6.7.7 Medical history and physical examination.
 - 8.6.7.8 Informed consent.
 - 8.6.7.9 Interpretation of ABO and Rh, and tests for infectious disease markers.
 - 8.6.7.10 Any adverse reaction to the administration.
 - 8.6.7.11 Engraftment data on the recipient, *if applicable*
- 8.6.8 The following records related to the administering of cellular therapy products are retained indefinitely – Allogeneic or Syngeneic Recipient Records
 - 8.6.8.1 Patient identification and recipient records
 - 8.6.8.2 Medical history and physical examination
 - 8.6.8.3 Informed consent
 - 8.6.8.4 Interpretation of ABO and Rh type, and tests for infectious disease markers, detection and identification of unexpected red cell antibodies, and red cell compatibility testing with the intended donor.
 - 8.6.8.5 Any adverse reaction to the administration
 - 8.6.8.6 Engraftment data on the transplant recipient, *if applicable*.
- 8.6.9 Administration Records
 - 8.6.9.1 Identification of all cellular therapy products administered, traceable to all donor information.
 - 8.6.9.2 Visual inspection before administration.
 - 8.6.9.3 All pertinent administration event information, including patient vital signs and time of all recorded event.
 - 8.6.9.4 Storage temperature charts and records, including temporary transport storage. See *STCL-EQUIP-021 Temperature and*

Environmental Monitoring Systems for Stem Cell Laboratory, STCL-EQUIP-021 JA1 Rees Scientific – Centron Presidio User Guide, STCL-EQUIP-021 JA2 Duke University Users Guide – Building Automation Systems, STCL-EQUIP-021 JA3 Duke University Users Guide – Hospital Refrigeration, STCL-EQUIP-021 JA4 Quick Guide to Responding to REES alarms.

8.6.10 Quality Control Records

- 8.6.10.1 Calibration of equipment.
- 8.6.10.2 Performance checks of equipment and reagents.
- 8.6.10.3 Periodic check of sterile technique.
- 8.6.10.4 Periodic tests of transport equipment.
- 8.6.10.5 Quality control testing results, interpretation, and corrective action for out-of-range results.
- 8.6.10.6 Results of external proficient testing, *if performed*.
- 8.6.10.7 Validation of equipment.

8.6.11 General Records

- 8.6.11.1 Training, continuing education and periodic competency testing of required personnel.
- 8.6.11.2 Maintenance records for equipment, including preventive maintenance.
- 8.6.11.3 Maintenance Cleaning Schedule for all Cellular Therapy programs are retained for three years.
- 8.6.11.4 Sterilization of supplies and reagents, *if applicable*.
- 8.6.11.5 Disposition of rejected supplies and reagents.
- 8.6.11.6 CQP audits and other assessment notes.
- 8.6.11.7 Names, signatures and initials or identification codes, and inclusive dates of employment of those authorized to sign, initial or review reports and records.
- 8.6.11.8 Employee qualifications, names, signatures, initials and inclusive dates of employment for all technical personnel directly involved in providing cellular therapy services.
- 8.6.11.9 Errors and accidents and resulting corrective action.
- 8.6.11.10 Reports of unsatisfactory or mislabeled products or adverse reactions, including reports of investigations
- 8.6.11.11 All archived procedures and policies.
- 8.6.11.12 Variances to established procedures.
- 8.6.11.13 Change Control documentation.

- 8.6.11.14 Divided responsibilities, *if/when applicable*.
- 8.6.11.15 If two or more facilities are involved in the collection and processing of a product, records shall show the responsibilities of each.
- 8.6.11.16 Each facility shall provide a copy of any requested records to the final receiving facility except for any compromising donor confidentiality.
- 8.6.11.17 Authorization letter of authority.

9 RELATED DOCUMENTS/FORMS

- 9.1 STCL-EQUIP-021 Temperature and Environmental Monitoring Systems for the STCL.
- 9.2 STCL-EQUIP-021 JA1 Rees Scientific Centron Presidio User Guide
- 9.3 STCL-EQUIP-021 JA2 Duke University Users Guide – BAS
- 9.4 STCL-EQUIP-021 JA3 Duke University Users Guide – Hospital Refrigeration
- 9.5 STCL-EQUIP-021 JA4 Quick Guide To Responding to REES Alarms.
- 9.6 STCL-GEN-015 JA1 EMMES System Advantage EDCSM
- 9.7 COMM-PAS-002 Records Retention Schedule
- 9.8 STCL-SOP-058 Laboratory Test Ordering
- 9.9 STCL-SOP-058 JA1 Ordering STCL Tests in Epic Beaker – Open Encounter
- 9.10 STCL-SOP-058 JA2 Ordering STCL Test in EPIC Beaker - Closed Encounter
- 9.11 STCL-SOP-058 JA3 Entering Test Results in EPIC Beaker
- 9.12 STCL-SOP-058 JA4 Maestro Care Quick Start Guide Beaker Clinical Pathology
- 9.13 STCL-GEN-015 JA3 Disposition of Labels and Barcodes
- 9.14 STCL-QA-005 Review of Processing Records
- 9.15 STCL-QA-005 FRM1 Apheresis Record Checklist
- 9.16 STCL-QA-005 FRM2 Infusion Record Checklist
- 9.17 STCL-QA-005 FRM3 Selection Record Checklist
- 9.18 STCL-QA-005 FRM4 Bone Marrow Harvest Record Checklist

10 REFERENCES

- 10.1 American Association of Blood Banks. Current edition.
- 10.2 Standards for Hematopoietic Progenitor Cell and Cellular Product. Current edition.
- 10.3 Foundation for the Accreditation of Hematopoietic Cell Therapy (FACT) and Netcord. International Standards for Cord Blood Collection, Processing, Testing, Banking, Selection and Release. Current edition.

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
07	M. Ritt	<ul style="list-style-type: none">Removed reference to Quality Systems Unit (QSU) throughout the document and replaced with Clinical Quality Program (CQP)

Signature Manifest

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