



**Duke**Medicine



**Pediatric Blood and Marrow Transplant  
Adult Blood and Marrow Transplant  
Stem Cell Laboratory**

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# **COMM-PAS-002**

## **RECORDS RETENTION SCHEDULE**

### **1 PURPOSE**

- 1.1 To describe the records retention schedule for the documents utilized in both the adult and pediatric transplant and cellular therapy programs, as well as those of the integrated cell collection program

### **2 INTRODUCTION**

- 2.1 The clinical program, including the integrated collections program shall maintain documents according to the retention schedule detailed in this procedure.
- 2.2 The Stem Cell Laboratory, which is the processing facility for the program, retains records in compliance with related procedure STCL-GEN-015 *Records Management*.

### **3 SCOPE AND RESPONSIBILITIES**

- 3.1 The clinical and collections programs' Medical Directors, and the Quality System Unit (QSU) are responsible for ensuring the requirements of this procedure are successfully met.

### **4 DEFINITIONS/ACRONYMS**

- 4.1 CBU Cord Blood Units
- 4.2 FACT Foundation for the Accreditation of Cellular Therapy
- 4.3 STCL Stem Cell Laboratory
- 4.4 QA Quality Assurance
- 4.5 QSU Quality Systems Unit

### **5 MATERIALS**

- 5.1 N/A

### **6 EQUIPMENT**

- 6.1 N/A

### **7 SAFETY**

- 7.1 N/A

### **8 PROCEDURE**

- 8.1 Requirements
  - 8.1.1 Records that shall be retained indefinitely:
    - 8.1.1.1 Donor Records
    - 8.1.1.2 Autologous Donors

- 8.1.1.2.1 Identifying information sufficient to attempt to contact the donor.
- 8.1.1.2.2 Medical history, interview, physical examination.
- 8.1.1.2.3 Informed consent.
- 8.1.1.2.4 Interpretations of ABO and Rh type, and tests for infectious disease markers, if applicable.
- 8.1.1.2.5 Adverse reactions or donor complaints related to regulatory issues.
- 8.1.1.3 Allogeneic Donors
  - 8.1.1.3.1 Identifying information sufficient to attempt to identify and contact the donor.
  - 8.1.1.3.2 Recipient information sufficient to permit tracking of the product.
  - 8.1.1.3.3 Medical history, interview, physical examination.
  - 8.1.1.3.4 Informed consent.
  - 8.1.1.3.5 Adverse reactions or donor complaints.
  - 8.1.1.3.6 Interpretation of ABO and Rh type, tests for infectious disease markers, detection and identification of unexpected red cell antibodies and, if performed, red cell compatibility testing.
- 8.1.1.4 Cord Blood Donors
  - 8.1.1.4.1 Identifying information sufficient to attempt to identify and contact the donor, or the donor's mother and/or father, if available.
  - 8.1.1.4.2 Informed consent of the donor's mother.
  - 8.1.1.4.3 Medical history, interview, physical examination of the donor's mother and the infant donor, where applicable.
  - 8.1.1.4.4 Interpretation of the donor's ABO and Rh type.
  - 8.1.1.4.5 Interpretation of tests for infectious disease markers performed on a sample from the donor's mother or the donor.
  - 8.1.1.4.6 Reasons for exclusions of cord blood units (CBU) collected but not banked.
- 8.1.1.5 Donor found unsuitable by the collection/processing service

- 8.1.1.5.1 Reason for deferral.
- 8.1.1.5.2 Record of donor notification of deferral, if applicable.
- 8.1.1.5.3 Record of products from unacceptable donors.
- 8.1.1.6 Facility Records
  - 8.1.1.6.1 Identifying information for all facilities providing donor selection information, product collection, processing or testing.
  - 8.1.1.6.2 Identifying information for all facilities providing recipient selection information, compatibility testing, record keeping, and treatment for disease or transplantation.
- 8.1.1.7 Processing Records
  - 8.1.1.7.1 Physician authorized for collection, if required.
  - 8.1.1.7.2 Product name, unique identifier, preparation volume and additives, date of collection and date of processing.
- 8.1.1.8 Details of product processing, including the following:
  - 8.1.1.8.1 Measurements of established collection and processing parameters.
  - 8.1.1.8.2 Manipulations other than minimal.
  - 8.1.1.8.3 Name, lot number, and expiration date of all reagents and supplies used during processing.
- 8.1.1.9 Labeling, including initials of personnel performing any container transfer.
- 8.1.1.10 Verification of the accuracy of the final container label before issue.
- 8.1.1.11 Name and address of the processing facility.
- 8.1.1.12 Quarantine Records
  - 8.1.1.12.1 Quality assurance and technical review of the donor chart.
  - 8.1.1.12.2 Medical director review and approval.
  - 8.1.1.12.3 Authorization to release any product with a positive infectious disease marker.
  - 8.1.1.12.4 Inspection of container at issue.

- 8.1.1.13 Storage and Distribution Records
  - 8.1.1.13.1 Reissuance, including temperature records.
  - 8.1.1.13.2 Final disposition of each product.
  - 8.1.1.13.3 Total inventory of stored products at any given time.
  - 8.1.1.13.4 Visual inspection of liquid components during storage and immediately before infusion.
  - 8.1.1.13.5 Storage temperature.
- 8.1.1.14 The following records related to the administering of cellular therapy products are retained indefinitely:
  - 8.1.1.14.1 Autologous recipient records
    - Patient identification and diagnosis.
    - Medical history and physical examination.
    - Informed consent.
    - Interpretation of ABO and Rh, and tests for infectious disease markers.
    - Any adverse reaction to the administration.
    - Engraftment data on the recipient, if applicable.
  - 8.1.1.14.2 Allogeneic or syngeneic recipient records
    - Patient identification and recipient records.
    - Medical history and physical examination.
    - Informed consent.
  - 8.1.1.14.3 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.
  - 8.1.1.14.4 Any adverse reaction to the administration.
  - 8.1.1.14.5 Engraftment data on the transplant recipient, if applicable.
  - 8.1.1.14.6 Administration records
    - Identification of all cellular therapy products administered, traceable to all donor information.
    - Visual inspection before administration.

- All pertinent administration event information, including patient vital signs and time of all recorded event.
- 8.1.1.14.7 Storage temperature charts and records, including temporary transport storage.
- 8.1.1.14.8 Quality control records
  - Calibration of equipment.
  - Performance checks of equipment and reagents.
  - Periodic check of sterile technique.
  - Periodic tests of transport equipment.
  - Quality control testing results, interpretation, and corrective action for out-of-range results.
  - Results of external proficient testing, if performed.
  - Validation of equipment.
- 8.1.1.15 General Records
  - 8.1.1.15.1 Training, continuing education and periodic competency testing of required personnel.
  - 8.1.1.15.2 Maintenance records for equipment, including preventive maintenance.
  - 8.1.1.15.3 Maintenance Cleaning Schedule for Stem Cell Laboratory.
  - 8.1.1.15.4 Sterilization of supplies and reagents.
  - 8.1.1.15.5 Disposition of rejected supplies and reagents.
  - 8.1.1.15.6 Quality Assurance (QA) audits and other assessment notes.
  - 8.1.1.15.7 Names, signatures and initials or identification codes, and inclusive dates of employment of those authorized to sign, initial or review reports and records.
  - 8.1.1.15.8 Employee qualifications, names, signatures, initials and inclusive dates of employment for all technical personnel directly involved in providing cellular therapy services.
  - 8.1.1.15.9 Errors and accidents and resulting corrective action.

- 8.1.1.15.10 Reports of unsatisfactory or mislabeled products or adverse reactions, including reports of investigations.
- 8.1.1.15.11 All archived procedures and policies.
- 8.1.1.15.12 Variances to established procedures.
- 8.1.1.15.13 Change Control documentation.
- 8.1.1.15.14 Divided responsibilities:
  - If two or more facilities are involved in the collection and processing of a product, records shall show the responsibilities of each.
  - Each facility shall provide a copy of any requested records to the final receiving facility except for those records that may compromise donor confidentiality.
  - Authorization letter of authority.

8.2 All records are maintained indefinitely.

## 9 RELATED DOCUMENTS/FORMS

9.1 STCL-GEN-015 Records Management

## 10 REFERENCES

- 10.1 American Association of Blood Banks, Standards for Hematopoietic Progenitor Cell and Cellular Product; current edition.
- 10.2 Foundation for the Accreditation of 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)
05	S. McCollum	<ul style="list-style-type: none"> <li>- Purpose and Introduction Section: updated to include the Collections Program.</li> <li>- Introduction Section: Content scope in relationship to the stem cell Lab (STCL) updated to reference related standard operating procedure (SOP): STCL-GEN-015.</li> <li>- Related Documents Section: updated to include STCL-GEN-015</li> <li>- Minor formatting updates throughout.</li> </ul>

## Signature Manifest

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