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COMM-PAS-002
RECORDS RETENTION SCHEDULE

1 PURPOSE
1.1 To describe the records retention schedule for clinical and cellular services program documents.

2 INTRODUCTION
2.1 The Adult and Pediatric Blood and Marrow Transplant Program (APBMT) and the Stem Cell Laboratory (STCL) shall maintain documents according to the retention schedule detailed in this procedure.

3 SCOPE AND RESPONSIBILITIES
3.1 This document is referenced when performing procedures involved in records retention for STCL and the Adult and Pediatric Blood and Marrow Transplant programs.
3.2 The APBMT Medical Directors, STCL Laboratory Manager, and the Quality System Unit (QSU) are responsible for ensuring the requirements of this procedure are successfully met.

4 DEFINITIONS/ACRONYMS
4.1 APBMT Adult and Pediatric Blood and Marrow Transplant
4.2 CBU Cord Blood Units
4.3 FACT Foundation for the Accreditation of Cellular Therapy
4.4 STCL Stem Cell Laboratory
4.5 QA Quality Assurance
4.6 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 N/A

10 REFERENCES


11 REVISION HISTORY

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<th>Author</th>
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<td>S. McCollum</td>
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COMM-PAS-002 Records Retention Schedule

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Management

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Medical Director

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Quality

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