DukeMedicine
Division of Cellular Therapy

ADULT AND PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

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Records Management

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APBMT-COMM-033
RECORDS MANAGEMENT

1 PURPOSE

1.1 The purpose of this procedure is to describe the necessary components of the records management system for the Adult and Pediatric Blood and Marrow Transplant (APBMT) Programs.

2 INTRODUCTION

2.1 The APBMT Programs shall establish, document, and maintain a records management system that encompasses the requirements listing in this procedure.

2.2 Documentation occurs in both electronic systems, utilizing the electronic medical record, and paper (shadow chart) systems. In the event the electronic medical record is not available, downtime procedures are followed in accordance with institutional policies and procedures.

2.3 The APBMT programs uses MasterControl for management of all program-owned standard operating procedures (SOPs).

3 SCOPE AND RESPONSIBILITIES

3.1 All personnel involved with the APBMT programs, including the program Medical Directors, and the Clinical Quality Program (CQP) are responsible for ensuring that the requirements of this procedure are successfully met.

4 DEFINITIONS/ACRONYMS

4.1	APBMT	Adult and Pediatric Blood and Marrow Transplant
4.2	DUH	Duke University Hospital
4.3	CQP	Clinical Quality Program
4.4	SOP	Standard Operating Procedure

5 MATERIALS

5.1 DUH data management system – Maestro Care (EPIC and Beaker)

5.2 MasterControl System – 21 CFR Part 11 compliant, validated document management system

6 EQUIPMENT

6.1 Computer

7 SAFETY

7.1 N/A

8 PROCEDURE

8.1 Requirements

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.

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 When recording data, ensure that all statements are clear and accurate.

8.1.7 As applicable, double verification should occur when transferring information (e.g. transferring information to labels) to prevent potential errors.

8.1.8 The recommended standard format to record dates are:

8.1.8.1 DDMMMYYYY (e.g. 02JAN2020)

8.1.8.2 MMDDYYYY (e.g. 01022020).

8.1.9 Signatures, whether electronic or hand-written, represent a legal statement about the accuracy of the completed activities.

8.1.10 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 as necessary.

8.2.4 Staff must legibly write new information on the record, and as appropriate, relate the new information to the existing information. Initial, date and provide rationale as necessary.

8.2.5 Deleting incorrect information where there is no correction, staff should draw a line through, then initial, date and provide rationale.

8.2.6 Recreated records shall be clearly designated as “duplicate” or “recreation”, shall be dated and initialed, and original attached if available.

8.2.7 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.

8.2.8 When the supervisor/manager is unable to correct, or resolve the documentation error, a deviation/investigation should be initiated. Refer to *COMM-QA-042 Deviations and Investigations.*

8.3 Handling Blood/Biologic Fluid Contaminated Documents Corrections

8.3.1 Small/minor contaminations: If no data is lost or can be transcribed and verified, remove the contaminated portion of the document. Note the rationale for this next to the portion of the document that has been removed. If this is not possible, a piece of clear adhesion tape may be placed over the spot of contamination.

8.3.2 Large/major contamination: Place the contaminated paperwork in a plastic bag or covering, duplicate the document using a photocopier, visually verify all duplicated data is legible, annotate “True and Exact copy of original” and the reason for duplications (e.g. “blood contamination”). Initial and date the copy and then destroy the contaminated paperwork. In circumstances where the above process is not practical/feasible due to circumstances such as the size of the document, an alternate course of action may be taken on a case specific basis upon consultation and approved by the CQP and/or Medical Director. The rationale for any non-standard action taken should be documented on the record in question and must not create a hazard for downstream document handlers.

8.4 Archival Requirements

8.4.1 Archived records will be readily 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.

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

8.5.1.2 There shall be an alternative system that ensures continuous operation in the event that computerized data entry is not available.

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

8.5.2 The Adult and Pediatric Blood and Marrow Transplant Programs use electronic data capture system, for electronic record management.

8.5.2.1 There shall be a system to limit access to authorized individuals. Individuals making entries shall be identifiable.

8.6 Records Retention Requirements

8.6.1 Records shall be maintained in such a way as to assure their preservation and protection from accidental or unauthorized modification.

8.6.2 Records containing confidential information shall be maintained in locked storage.

8.6.3 Records shall be readily retrievable.

8.7 All records are maintained indefinitely and/or in accordance with DUH policy (See DUH Policy: Retention, Preservation and Destruction of Records)

8.7.1 An updated list of records to include timeframes for review, storage location and medium, and retention periods shall be maintained.

8.7.2 For additional information regarding records retention requirements, see related policies:

8.7.2.1 COMM-PAS-002 *Records Retention Schedule*

8.7.2.2 DUH Policy: *Retention, Preservation and Destruction of Records*

9 RELATED DOCUMENTS/FORMS

9.1 COMM-PAS-002 Records Retention Schedule

9.2 COMM-QA-042 Deviations and Investigations

9.3 DUH Policy: Retention, Preservation and Destruction of Records

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 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)
05	M. Ritt	Removed reference to Quality Systems Unit (QSU) throughout the document and replaced with Clinical Quality Program (CQP)

Signature Manifest

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