ADULT AND PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

**DOCUMENT NUMBER:** APBMT-COMM-033

**DOCUMENT TITLE:**
Records Management

**DOCUMENT NOTES:**

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**Document Information**

- **Revision:** 03
- **Vault:** APBMT-Common-rel
- **Status:** Release
- **Document Type:** Common

**Date Information**

- **Creation Date:** 05 Sep 2014
- **Release Date:** 11 May 2015
- **Effective Date:** 11 May 2015
- **Expiration Date:**

**Control Information**

- **Author:** ALLIS006
- **Owner:** JLF29
- **Previous Number:** APBMT-COMM-033 Rev 02
- **Change Number:** APBMT-CCR-049
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 Programs

2 INTRODUCTION
2.1 The Adult and Pediatric Blood and Marrow Transplant Programs shall establish,
document, and maintain a records management system that encompasses the
requirements listing in this procedure. Documentation occurs in both electronic
and paper (shadow chart) systems. Duke electronic documentation system is
Maestro Care. EPIC is used for patient documentation and Beaker is utilized for
laboratory. The APBMT program uses Master Control for management of all
SOPs.

3 SCOPE AND RESPONSIBILITIES
3.1 The Adult and Pediatric Medical Directors, and the Quality Systems Unit are
responsible for ensuring that the requirements of this procedure are successfully
met.

3.2 All personnel involved with the APBMT program are responsible for ensuring
that the requirements of this procedure are successfully met.

4 DEFINITIONS/ACRONYMS
4.1 QSU Quality Systems Unit

5 MATERIALS
5.1 DUH data management system – Maestro Care (EPIC and Beaker)
5.2 Master Control 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 Signatures, whether electronic or hand-written, represent a legal statement about the accuracy of the completed activities.
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 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.

8.3 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.
8.5.1.1 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 uses 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. Records shall be readily retrievable.
8.6.2 Records containing confidential information shall be maintained in locked storage.
8.6.3 An updated list of records to include timeframes for review, storage location and medium, and retention periods shall be maintained.

9 RELATED DOCUMENTS/FORMS
9.1 NA

10 REFERENCES
### 11 REVISION HISTORY

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<th>Author</th>
<th>Description of Change(s)</th>
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| 03           | J. Allison | Added Section 11 Revision History.  
Added Section 3.2 All personnel involved with the APBMT program are responsible for ensuring that the requirements of this procedure are successfully met.  
Section 2.1 – removed browser – added Maestro Care/EPIC/Beaker and Master Control  
Section 5.1 – removed browser – added Maestro Care/EPIC  
Deleted Section 8.8 and 8.8.2 – duplicate of 8.5  
Deleted Section 8.7 – duplicate of Section 8.4 |
# Signature Manifest

**Document Number:** APBMT-COMM-033  
**Revision:** 03  
**Title:** Records Management

All dates and times are in Eastern Time.

## APBMT-COMM-033 Records Management

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### Management

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