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

DOCUMENT NUMBER: COMM-PAS-011

DOCUMENT TITLE:

Electronic Record Systems for Clinical Programs: PBMT Database

DOCUMENT NOTES:

Document Information

Revision: 02

Vault: COMM-PAS-rel

Status: Release

Document Type: COMM-PAS

Date Information

Creation Date: 29 Jul 2021

Release Date: 16 Aug 2021

Effective Date: 16 Aug 2021

Expiration Date:

Control Information

Author: BS76

Owner: VINES003

Previous Number: COMM-PAS-011 Rev 01

Change Number: PAS-CCR-042

COMM-PAS-011
ELECTRONIC RECORD SYSTEMS FOR CLINICAL PROGRAMS: PBMT DATABASE

1   PURPOSE

1.1   This procedure presents a guidance to define the process for ensuring the maintenance of accuracy, integrity, identity and confidentiality of the Pediatric Blood and Marrow Transplant (PBMT) Database electronic record system.

2   INTRODUCTION

2.1   The PBMT Database electronic record system plays a core function in the clinical and research systems of the PBMT program. A Standard Operating Procedure (SOP) with policies and system elements is required to maintain the accuracy, integrity, identity, and confidentiality of this electronic record system.

3   SCOPE AND RESPONSIBILITIES

3.1   This procedure applies to the development, modification, maintenance or application of the PBMT Database electronic record system.

3.2   The developer(s) involved in the development, modification, and maintenance of the PBMT Database electronic record outlined in this document are responsible for ensuring the requirements of this procedure are met.

4   DEFINITIONS/ACRONYMS

4.1   CIBMTR   Center for International Blood & Marrow Transplant Research

4.2   EMR   Electronic Medical Record

4.3   FACT   Foundation for the Accreditation of Cellular Therapy

4.4   PBMT   Pediatric Blood and Marrow Transplant

4.5   QSU   Quality Systems Unit

4.6   SOP   Standard Operating Procedure

5   MATERIALS

5.1   N/A

6   EQUIPMENT

6.1   N/A

7   SAFETY

7.1   N/A

8 PROCEDURE

8.1   The PBMT clinical program defines "Critical Electronic Records" as any system, not including the electronic medical health record or other hospital-based systems, under the control of the Clinical Program that is used as a substitute for paper, to perform calculations, or used to store information, each for the purpose of making clinical decisions related to the diagnosis and treatment of patients, or to document treatment-related outcomes.

8.2   The PBMT Database contains critical electronic records, such as patient demographics and basic transplant data, and it is used for scheduling and reporting. This procedure ensures that for the PBMT Database critical electronic record, there is a system or method in place to:

8.2.1   Define development requirements, function, authorization, and sign off by the Medical Director or designee, and the Quality Systems Unit (QSU).

8.2.1.1   This information will be contained in the *PBMT Database Validation Plan* and *PBMT Database Validation Requirements* documents.

8.2.2   Ensure maintenance of data accuracy, integrity, identity, and confidentiality within each record.

8.2.2.1   Data cross-checks will be performed for critical fields in the PBMT Database with the hospital Electronic Medical Record (EMR) (MaestroCare/EPIC) and the Center for International Blood & Marrow Transplant Research's (CIBMTR) dataset. Results, including discrepancies, will be documented and reported.

8.2.3   Ensure individuals utilizing the electronic record are accurately trained on its use.

8.2.3.1   The *PBMT Database User Training Log* REDCap™ project will be used for user training and storage of training records.

8.2.4   Limit access to authorized individuals.

8.2.4.1   Access will require NetID/Windows authentication, network share access, and inclusion in a user access table.

8.2.5   Maintain unique identifiers, where applicable.

8.2.6   Perform record entry, including review of data before final acceptance, record verification, and record revision.

8.2.6.1   A second verification of modified data (aside from new record entry) after initial saving of data will be required.

8.2.7   Identify the individual responsible for each record entry.

8.2.7.1   An audit table will capture all data modification.

8.2.8   Ensure record protection and enable their accurate and ready retrieval throughout the period of record retention.

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8.3   The validation steps for the PBMT Database critical electronic record include the following, based on applicability as recommended by the Foundation for the Accreditation of Cellular Therapy (FACT) guidance 8th edition are detailed in the *PBMT Database Validation Plan* and *PBMT Database Validation Requirements* documents and include the following:

    8.3.1   Documentation of development requirements and function.

    8.3.2   Verification that calculations are performed correctly.

    8.3.3   Evidence that records reproducibly contained the desired information.

    8.3.4   A method of data verification before final entry.

    8.3.5   Internal consistency checks to verify values are within defined ranges.

    8.3.6   Restricted entry of data to matched predefined value limits.

    8.3.7   Required entry of data with field information limited with choices for data consistency.

    8.3.8   Documentation of the database system, including written methods for data entry and generation of printed reports that include all information entered into the database, acceptable sources of the entered data, and a description of system maintenance and development history.

    8.3.9   Formal and documented training in system use requirements for all personnel.

    8.3.10   Regular quality audit trails.

    8.3.11   A mechanism to report deviations to report and resolve problems.

       8.3.11.1   The *PBMT Database User Feedback REDCap™* project will be used to report deviations, errors, and requests.

    8.3.12   Evidence that changes to records do not obscure previous entries.

8.4   The hospital EMR will be the alternative system for information retrieval in the event of "downtime" for the PBMT Database critical electronic record.

8.5   The PBMT Database application can generate reports and export datasets (which are true copies) of the records in both human and electronic format suitable for inspection and review.

8.6   There are validated procedures for and documentation, stored on the PBMT secured network share, of each of the following for the PBMT Database critical electronic record:

    8.6.1   Systems Development.

    8.6.2   Training and continued competency of personnel in systems use.

    8.6.3   Monitoring of data integrity – which includes establishing assurances that data has not been changed either by accident or by intent and requires access to original documents whenever possible, along with a plan for verification of the electronic system data by comparison to original data.

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8.6.4   Back-up of the system on a regular defined schedule.

8.6.5   System assignment of unique identifiers, where applicable.

8.7   The validation requirements of the PBMT Database will be described in the PBMT Database Requirements Document.

8.8   Validation records will be created and maintained using the PBMT Validation Plan.

8.9   All required documents not stored in MasterControl will be stored on a protected network drive.

8.10 Completed Validations will be dated and signed by the person performing the validation, the QSU and other personnel as needed per COMM-QA-044 Approaches to Validation. Validations are retained by the QSU.

9   RELATED DOCUMENTS/FORMS

9.1   COMM-QA-044 Approaches to Validation

9.2   COMM-PAS-008 Electronic Record Systems for Clinical Programs

9.3   PBMT Database Validation Plan

9.4   PBMT Database Validation Requirements

9.5   PBMT Database Critical Field List

9.6   PBMT Database User Guide and System Documentation

9.7   PBMT Database Validation and Test Grid

10   REFERENCES

10.1   FACT-JACIE. (2021). International Standards for Hematopoietic Cellular Therapy Production Collection, Processing, and Administration. Current Version.

11   REVISION HISTORY

Revision No.	Author	Description of Change(s)
02	Bing Shen	Section 8.3: Changed the edition number of FACT-JACIE International Standards from 7th to 8th Section 10.1: Changed the referenced year of publication of FACT- JACIE standards from 2018 to 2021

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Signature Manifest

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All dates and times are in Eastern Time.

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Document Release

Name/Signature	Title	Date	Meaning/Reason
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