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

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Electronic Record Systems for Clinical Programs: ABMT Database

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COMM-PAS-010
ELECTRONIC RECORD SYSTEMS FOR CLINICAL PROGRAMS: ABMT DATABASE

1 PURPOSE

1.1 This procedure presents a guidance to define the process for ensuring the accuracy, integrity, identity and confidentiality of electronic records under the control of the Adult Blood and Marrow Transplant (ABMT) Clinical Program, namely those electronic records contained in the ABMT Database.

1.2 This procedure does not apply to all portions of the ABMT Database, but mainly to those areas with data elements used for the Foundation for the Accreditation of Cellular Therapy (FACT) Quality Assessment (QA) Analysis.

1.3 This procedure contains the minimum requirements for validation.

2 INTRODUCTION

2.1 The ABMT Database plays a core function in the clinical and quality systems of the ABMT program. In as such, Standard Operating Procedures (SOPs), policies, and system elements are required to maintain the accuracy, integrity, identity, and confidentiality of each.

3 SCOPE AND RESPONSIBILITIES

3.1 This procedure applies to the development, modification, maintenance or application of Critical Electronic Records which reside in the ABMT Database.

3.2 All personnel involved in the development, maintenance, and use of the ABMT Database are responsible for ensuring the requirements of this procedure are met.

3.3 The scope is limited to those data elements, or fields, that are deemed critical. A list of these elements can be found in the related document **ABMT Database Critical Field List**.

4 DEFINITIONS/ACRONYMS

4.1	ABMT	Adult Blood and Marrow Transplant
4.2	FACT	Foundation for the Accreditation of Cellular Therapy
4.3	QA	Quality Assessment
4.4	QSU	Quality Systems Unit
4.5	SOP	Standard Operating Procedure

5 MATERIALS

5.1 NA

6 EQUIPMENT

6.1 NA

7 SAFETY

7.1 NA

8 PROCEDURE

8.1 The clinical program will maintain a current listing of all critical fields within the ABMT Database. See **ABMT Database Critical Field List** document.

8.2 The clinical program defines "Critical Data Fields" as data elements under the control of the Clinical Program stored in the ABMT Database and used to perform calculations or store information for the purpose of making clinical decisions related to the diagnosis and treatment of patients, or to document treatment-related outcomes for QA analysis.

8.3 The ABMT Program has systems and methods in place regarding the ABMT Database to:

8.3.1 Document the development requirements and function.

8.3.2 Ensure the data accuracy, integrity, identity and confidentiality within each critical data element.

8.3.3 Train new users on the use of the database and keep a record of that training.

8.3.4 Restrict access to the database to only authorized individuals.

8.3.5 Provide unique identifiers for every critical data record.

8.3.6 Allow data to be entered, reviewed, verified and modified.

8.3.7 Audit who adds, deletes or modifies a record, and when it is done.

8.3.8 Ensure record protection and accurate retrieval.

8.4 The basic validation requirements of the ABMT Database will be described in the **ABMT Database Requirements Document**.

8.5 Validation records will be created and maintained using the **ABMT Database Validation Template**.

8.6 All required documents that are not stored in MasterControl will be kept on the department's shared drive.

8.7 Historical periods of downtime involving the ABMT Database have nearly always been minimal in nature. However, if it is inaccessible for an extended period of time, then the Duke Electronic Medical Record (Maestro Care / Epic) can be used to obtain any of the necessary critical data. Validation and training for that system is beyond the scope of this document.

8.8 The ability to view the critical data will be available either via printed reports from within the database or screenshots. If necessary, electronic copies of the database can be made.

8.9 Completed Validations will be dated and signed by the person performing the validation, the Quality Systems Unit (QSU) and other personnel as needed per

COMM-QA-044 Approaches to Validation. Original copies will be retained by the end user and a copy sent to QSU to be stored in the QSU validation database.

8.10 Changes to validated critical electronic records will be managed and reviewed using the change control process per COMM-PAS-004 *Change Control*.

9 RELATED DOCUMENTS/FORMS

9.1 COMM-QA-044 Approaches to Validation

9.2 COMM-PAS-004 Change Control

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

9.4 ABMT Database Critical Field List

9.5 ABMT Database Requirements Document

9.6 ABMT Database Validation Template

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 10.1: Changed the referenced year of publication of FACT- JACIE standards from 2018 to 2021

Signature Manifest

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