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

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COMM-PAS-008

ELECTRONIC RECORD SYSTEMS FOR CLINICAL PROGRAMS

1 PURPOSE

- 1.1 This procedure presents a guidance to define the process for ensuring the maintenance of accuracy, integrity, identity and confidentiality of electronic records under the control of the Adult and Pediatric Blood and Marrow Transplant (APBMT) Clinical Programs and the Stem Cell Laboratory (STCL). These programs include the scope of cellular therapy.
- 1.2 This procedure does not apply to the hospital-based systems, such as the electronic medical health record or to electronic record systems outside of the control of the APBMT Clinical Programs.
- 1.3 This procedure contains a current listing of all critical electronic record systems and the minimum requirements for validation.

2 INTRODUCTION

- 2.1 Electronic records play a core function in the clinical and quality systems of the APBMT programs. 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 and application of critical electronic records under the scope of the APBMT Clinical Programs.
- 3.2 All personnel involved in the development, maintenance, and use of any critical electronic record outlined in this document are responsible for ensuring the requirements of this procedure are met.

4 DEFINITIONS/ACRONYMS

- 4.1 APBMT Adult and Pediatric Blood and Marrow Transplant
- 4.2 FACT Foundation for the Accreditation of Cellular Therapy
- 4.3 SOP Standard Operating Procedure
- 4.4 STCL Stem Cell Laboratory
- 4.5 QSU Quality Systems Unit

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 electronic record systems as defined in this procedure. See Table 1.
- 8.2 The 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.

Table 1. Critical Electronic Record Systems List	
Name of System	Description
ABMT Database	Contains ABMT Patient, Transplant and Protocol data, and includes aspects of cellular therapy for the adult program.
Cell Therapy Screening – REDcap	Contains potential patients for brain injury studies.
MasterControl	A validated software product from MasterControl, Inc. This system is the main document control agent that provides automated workflow, document management capabilities, event management, and training in a configurable software system. MasterControl addresses stringent regulations and standards to ensure compliance (21 CFR Part 11).
PBMT Database	Contains PBMT patient demographics and basic transplant data, and includes aspects of cellular therapy for the pediatric program. Used for scheduling and reporting.
STCL EMMES Database	Data Repository.
Transplant and Cellular Therapy Outcomes Database	A suite of statistical analysis programs used to monitor neutrophil and platelet engraftment, relapse, transplant-related mortality, overall survival, and graft versus host disease, as applicable, for Bone and Marrow Transplants, Immune Effector Cell Therapy, and Donor Lymphocyte Infusions.

- 8.3 For each critical electronic record, database or tool, there will be a system or method in place to:
 - 8.3.1 Define development requirements and function.
 - 8.3.2 Ensure maintenance of data accuracy, integrity, identity, and confidentiality within each record.
 - 8.3.3 Ensure individuals utilizing the electronic record are accurately trained on its use.
 - 8.3.4 Limit access to authorized individuals.
 - 8.3.5 Maintain unique identifiers, where applicable.
 - 8.3.6 Perform record entry, including review of data before final acceptance, record verification, and record revision.
 - 8.3.7 Identify the individual responsible for each record entry.
 - 8.3.8 Ensure record protection and enable their accurate and ready retrieval throughout the period of record retention.
- 8.4 Each critical electronic record will have its own SOP to define key aspects of use and management.
- 8.5 When developing validation steps for each critical electronic record, the following should be considered for inclusion based on applicability as recommended by the Foundation for the Accreditation of Cellular Therapy (FACT) guidance 8th edition. Current recommendations will be reviewed at time of validation development for any changes/updates which may have occurred:
 - 8.5.1 Documentation of development requirements and function.
 - 8.5.2 Verification that calculations are performed correctly.
 - 8.5.3 Evidence that records reproducibly contain the desired information.
 - 8.5.4 Tests of system function under “worst” case scenarios, such as system overloads and power failures.
 - 8.5.5 A method of data verification before final entry.
 - 8.5.6 Internal consistency checks to verify values are within defined ranges.
 - 8.5.7 Restricted entry of data to match predefined value limits.
 - 8.5.8 Required entry of data with field information limited by choices for data consistency.
 - 8.5.9 Source data is derived from pre-defined sources such as fixed forms.
 - 8.5.10 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.
 - 8.5.11 Formal and documented training in system use requirements for all personnel.

- 8.5.12 Evidence of SOPs in place for computer record-keeping systems.
- 8.5.13 Regular quality audit trails.
- 8.5.14 A mechanism to report deviations to report and resolve problems.
- 8.5.15 Evidence that changes to records do not obscure previous entries.
- 8.5.16 Documentation that deleted electronic files have been converted to non-electronic media such as microfilm, microfiche and paper in a manner that preserves the content and meaning of the record.
- 8.6 There will be defined processes for an alternative system for information retrieval in the event of “downtime” for each critical electronic record, database, or tool.
 - 8.6.1 There will be validation of these processes.
 - 8.6.2 There will be training of staff on this alternative system.
- 8.7 There will be the ability to generate true copies of the records in both human readable and electronic format suitable for inspection and review.
- 8.8 There will be validated procedures for and documentation of each of the following for each critical electronic record:
 - 8.8.1 Systems Development.
 - 8.8.2 Training and continued competency of personnel in systems use.
 - 8.8.3 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.
 - 8.8.4 Back-up of the system on a regular defined schedule.
 - 8.8.5 System assignment of unique identifiers, where applicable.
- 8.9 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*. 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

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)
05	Bing Shen	<ul style="list-style-type: none">• Table 1 updated to reflect current naming nomenclature

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