DukeMedicine

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

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Electronic Record Systems for Clinical Programs: Brain Injury REDCap

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COMM-PAS-012
ELECTRONIC RECORD SYSTEMS FOR CLINICAL PROGRAMS: BRAIN INJURY REDCap

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 Brain Injury REDCap electronic record system, which is a collection of database projects built on the REDCap™ web platform.

2 INTRODUCTION

2.1   The Brain Injury REDCap electronic record system plays a core function in the clinical and research systems of the Pediatric Blood and Marrow Transplantation (PBMT) program and the Marcus Center for Cellular Cures (MC3) program. A Standard Operating Procedure (SOP) with policies and system elements are 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 Brain Injury REDCap electronic record system.

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

4 DEFINITIONS/ACRONYMS

4.1   BI   Brain Injury

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   MC3   Marcus Center for Cellular Cures

4.6   QSU   Quality Systems Unit

4.7   SOP   Standard Operating Procedure

5 MATERIALS

5.1   NA

6 EQUIPMENT

6.1   NA

7 SAFETY

7.1   NA

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8   PROCEDURE

8.1   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.

8.2   This procedure ensures that for the Brain Injury REDCap 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 *Brain Injury REDCap Validation Plan* and *Brain Injury REDCap Validation Requirements* documents.

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

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

        8.2.3.1   The *BI REDCap 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   REDCap™ uses secure web authentication and requires a Duke NetID and password along with designated access to the REDCap™ project.

    8.2.5   Maintain unique identifiers, where applicable.

        8.2.5.1   All records have a unique identifier enforced by the system.

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

    8.2.7   Identify the individual responsible for each record entry.

        8.2.7.1   The REDCap™ platform maintains a log of all data modifications.

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

8.3   The validation steps for the Brain Injury REDCap 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 *Brain Injury REDCap Validation Plan* and *Brain Injury REDCap 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.

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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.

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

8.4   The hospital electronic medical record (EMR) will be the alternative system for information retrieval in the event of "downtime" for the Brain Injury REDCap critical electronic record.

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

8.6   There are validated procedures for and documentation, stored on the departmental secured network share, of each of the following for the Brain Injury REDCap 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.

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 Brain Injury REDCap will be described in the *Brain Injury REDCap Validation Requirements* document.

8.8   Validation records will be created and maintained using the *Brain Injury REDCap Validation Plan* document.

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

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8.10   Completed Validations will be dated and signed by the person performing the validation, the Medical Director or designee, and the QSU 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   Brain Injury REDCap Validation Plan

9.4   Brain Injury REDCap Validation Requirements

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

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Signature Manifest

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