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|  | <b>Policy</b> | Document #: 6.1.006<br>Revision: 0<br>Valid Date: 10/31/2019<br>Page 1 of 2<br>Effective Date: 10/31/2019 |
| <b>Data Audit Policy</b>  |               |   |

## 1.0 Purpose

This policy establishes the guidelines for compliance with the data management standards in the *FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration*.

## 2.0 Scope

This policy applies to clinical programs seeking or maintaining FACT Accreditation under the *FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration*.

## 3.0 Responsibility

- 3.1 It is the responsibility of FACT to ensure that clinical programs have access to this policy and that it is followed.
- 3.2 It is the responsibility of programs seeking or maintaining FACT Accreditation to follow this policy.

## 4.0 References N/A

## 5.0 Definitions

- 5.1 Probation: A period of time during which a program has not met specific defined criteria and is at risk of losing FACT accreditation if additional requirements are not met. This status will be documented in a program's FACT application, report, and/or internal FACT records. This status is confidential and will not be published or released.

## 6.0 Procedure

- 6.1 Compliance with Standard B9 [Data Management] is required to maintain FACT accreditation in good standing. Compliance is documented by one of the following.
  - 6.1.1 Passing the most recent CIBMTR audit with a  $\leq 3.0\%$  critical field error rate AND
    - 6.1.1.1 If systemic errors were not identified and the critical field error rate was:
      - $< 2.0\%$ , no further action is required of the program.
      - $\geq 2.0\%$  and  $\leq 3.0\%$ , the program must submit a satisfactory internal data accuracy audit report to the FACT-CIBMTR Data Audit Committee on a timeline determined by the committee.
    - 6.1.1.2 If systemic errors were identified, the program must make satisfactory progress in CAP requirements, regardless of the critical field error rate.
  - 6.1.2 Programs not audited by CIBMTR are required to submit milestone reports to FACT every six (6) months or an approved alternative.
    - 6.1.2.1 Milestone reports will be required until the program completes a CIBMTR audit.

- 6.1.3 Programs not submitting data to CIBMTR will be encouraged to submit data and will be required to submit milestone reports to the FACT-CIBMTR Data Audit Committee every six (6) months or follow an approved alternative.
- 6.2 The FACT-CIBMTR Data Audit Committee determines a program's compliance with Standard B9, determines if a program's progress and submissions are satisfactory, and makes recommendations to the FACT Cellular Therapy Accreditation Committee.
  - 6.2.1 Programs must comply with requirements of the FACT-CIBMTR Data Audit Committee.
- 6.3 The passing score for a CIBMTR audit will be adjusted as necessary to agree with any change in the CIBMTR definition of a passing score.
- 6.4 Programs with >3.0% critical field error rate will have failed the audit.
  - 6.4.1 Following the first audit failure, a program will be placed on probation. Programs on probation remain accredited and are listed on the FACT website.
    - 6.4.1.1 Continued status as an accredited program is contingent on satisfactory submission of all corrective action plans, internal data audit reports, and milestone reports as determined by CIBMTR and the FACT-CIBMTR Data Audit Committee.
    - 6.4.1.2 Failure to comply with requirements of CIBMTR or the Data Audit Committee may put continued accreditation at risk.
  - 6.4.2 Following a second consecutive audit failure, a program's accreditation may be suspended. Reaccreditation will require a passing CIBMTR audit and may require a reinspection by FACT.
  - 6.4.3 Programs may request an interim CIBMTR audit at the program's expense, auditing data since the corrective actions were implemented. Interim audits resulting in a:
    - 6.4.3.1 Passing critical field error rate will remove a program from probation.
    - 6.4.3.2 Failing critical field error rate will not count as a second failing audit.
- 6.5 CIBMTR audit results after October 1, 2016 will be considered when applying audit consequences.
- 6.6 Issues identified during CIBMTR data audits related to informed consent are not part of this policy.
- 6.7 Programs must continue to submit corrective action plans and milestone reports according to CIBMTR policies and requirements.

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| Document Approvals:   |   |   |
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