

 <p>FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY AT THE UNIVERSITY OF NEBRASKA MEDICAL CENTER Policies and Procedures</p>	<p>Policy</p>	<p>Document #: ACC.6.1.006 Revision: 1 Approval Date: 03/19/2021 Page 1 of 3 Effective Date: 03/20/2021</p>
<p>Data Audit Policy</p>		

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.
- 3.3 It is the responsibility of the FACT – CIBMTR Data Audit Committee to:
 - 3.3.1 Review corrective action plans, implementation progress of the corrective actions, and audit reports from recent audits performed to assess effectiveness of the corrective actions.
 - 3.3.2 Make resources for reviewing, assessing, and improving data accuracy available.
 - 3.3.3 Provide education.

4.0 References - NA

5.0 Definitions and Abbreviations

- 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 This status is confidential and will not be published or released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 Policy

- 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 summary reports to FACT every six (6) months or an approved alternative.
- 6.1.2.1 Summary 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 summary reports to the FACT-CIBMTR Data Audit Committee every six (6) months or follow an approved alternative.
- 6.1.4 A Clinical Program applying for initial FACT Accreditation should have passed its most recent CIBMTR Data Audit if one was performed.
- 6.1.4.1 If the applicant program failed the most recent Data Audit with a critical field error rate that triggered CIBMTR consequences, the Program must demonstrate significant improvement on an interim CIBMTR audit prior to initial on-site FACT inspection. If the interim audit shows significant improvement but is still not passing, the Program may proceed with the accreditation process and on-site inspection.
- 6.1.4.2 If the failing CIBMTR audit did not trigger CIBMTR consequences, the Program may proceed with the accreditation process and on-site inspection, and the most recent CIBMTR audit will count toward FACT consequences.
- 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 progress on implementation of the corrective action plan, 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 failing a CIBMTR audit that triggered CIBMTR consequences 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 and FACT accreditation 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.

Approved by (date):

Heather Conway (Quality Manager) (03/19/2021), Linda Miller (Chief Executive Office) (03/18/2021),
Phyllis Warkentin (Chief Medical Officer) (03/18/2021)