 <p>Policies and Procedures</p>	<p>Policy</p>	<p>Document #: ACC.6.1.007 Revision: 2 Approval Date: 20/December/2022 Page 1 of 6 Effective Date: 20/December/2022</p>
<p>Clinical Outcomes Corrective Action Plan Policy</p>		

1.0 Purpose

This policy establishes guidelines for compliance with the recommendation in the *FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration* to achieve one-year survival within or above the expected range when compared to national or international outcome data, and related requirements for submission of corrective action plans (CAPs) when not achieved.

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.
- 3.2 It is the responsibility of Clinical Programs seeking or maintaining FACT accreditation to follow this policy.
- 3.3 It is the responsibility of the Clinical Outcomes Improvement Committee to:
 - 3.3.1 Review CAPs for adequacy and appropriateness.
 - 3.3.2 Make resources for reviewing, assessing, and improving clinical outcomes available.
 - 3.3.3 Provide education.

4.0 References

- 4.1 Center for International Blood and Marrow Transplant Research (CIBMTR) Transplant Center-Specific Survival Report (current report)
- 4.2 FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration (current edition)
- 4.3 LeMaistre, CF, Wacker KK, Akard, LP, Al-Homsi, AS, Gastineau, DA, Godder, K, Lill, M, Selby, GB, Steinberg, A, Anderson, JA, Leahigh, AK, Warkentin, PI. Integration of publicly reported center outcomes into standards and accreditation: The FACT model. *Biology of Blood and Marrow Transplantation*. 2019; **25**: 2243-2250: [https://www.astctjournal.org/article/S1083-8791\(19\)30419-7/fulltext](https://www.astctjournal.org/article/S1083-8791(19)30419-7/fulltext).
- 4.4 Review of Corrective Action Plans to Improve Clinical Outcomes, ACC.6.6.008

4.5 [Suspension or Termination of Accreditation](#), ACC.6.1.005

5.0 Definitions and Abbreviations

- 5.1 CAP: Corrective Action Plan
- 5.2 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 the FACT-JACIE Standards is required to maintain FACT accreditation in good standing. Compliance with requirements related to one-year survival compared to national or international data is documented by one of the following:
 - 6.1.1 A Clinical Program meets or exceeds the expected outcomes for one-year survival.
 - 6.1.1.1 Allogeneic transplant programs in the United States must meet the expected range as reported by the annual CIBMTR Transplant Center-Specific Survival Report.
 - 6.1.1.2 Autologous-only transplant programs or transplant programs outside of the United States must determine that they meet expected one-year survival compared to national or international data.
 - 6.1.2 A Clinical Program that does not at least meet the expected outcomes for one-year survival as described above must implement a CAP that meets FACT requirements and submit the CAP to FACT.
- 6.2 The Clinical Outcomes Improvement Committee reviews the CAP and subsequent updates, and recommends next steps to the FACT Cellular Therapy Accreditation Committee.
 - 6.2.1 The process for submitting and reviewing CAPs is outlined in Appendix A, *FACT Process for Reviewing Corrective Action Plans*.
 - 6.2.2 The Clinical Outcomes Improvement Committee reviews the CAP and interacts directly with the Clinical Program during the years there is not an on-site FACT inspection.
 - 6.2.3 Potential findings are outlined in Appendix B, *CAP Determinations*.
 - 6.2.3.1 After the Clinical Outcomes Improvement Committee determines that corrective actions have been implemented, data show sustained improvement in one-year survival, and the program has met expected survival, updates regarding the CAP will no longer be required. The Clinical Program will continue to update FACT annually of its one-year survival compared to the CIBMTR report or other data, as applicable.

6.2.3.2 If the risk-adjusted one-year survival remains lower than the expected range and does not improve for three consecutive reporting years, the Clinical Outcomes Improvement Committee will formally evaluate the program's ability and effort to improve survival in accordance with *Review of Corrective Action Plans to Improve Clinical Outcomes*.

- The committee will consider data published by the CIBMTR, timeliness and accuracy of program submissions, internal survival data submitted by the program, and extenuating factors.
- If the committee determines the program has not demonstrated sufficient ability or effort, the program will be placed on probation and may be required to complete a focused reinspection. A meeting with the Program Director will be conducted to determine the scope, purpose, and timing of the reinspection based on the program's deficiencies in evaluating and improving one-year survival, if required.
- If the program does not demonstrate satisfactory correction of the deficiencies, the program's accreditation may be suspended in accordance with [*Suspension or Termination of Accreditation*](#). The committee will determine the timeframe in which deficiencies must be corrected and one-year survival must improve.
- Failure to demonstrate correction of the deficiencies within the established timeframe may result in termination of the accreditation.

6.3 CAP Guidelines

6.3.1 CAPs must:

- 6.3.1.1 Identify specific causes of death.
- 6.3.1.2 State current 100-day and 1-year overall survival and treatment-related mortality based on internal outcomes analysis.
- 6.3.1.3 Provide quantitative data.
- 6.3.1.4 Identify reasonable causes of the low one-year survival rate.
- 6.3.1.5 Address the identified causes.

6.3.2 Updates to the CAP must be submitted at the time of inspection, at the time of the Annual Report, and as otherwise directed by the Clinical Outcomes Improvement Committee. These subsequent submissions must:

- 6.3.2.1 Update quantitative data provided in the initial CAP.
- 6.3.2.2 Provide additional information requested by the committee.
- 6.3.2.3 Include a timeline of implementation of corrective actions.

- 6.3.2.4 Include an assessment of the corrective actions' effectiveness.
- 6.3.2.5 Demonstrate a measurable outcome improvement, or, if outcomes do not improve, include a reassessment of root causes and appropriate revised corrective actions based on that reassessment.

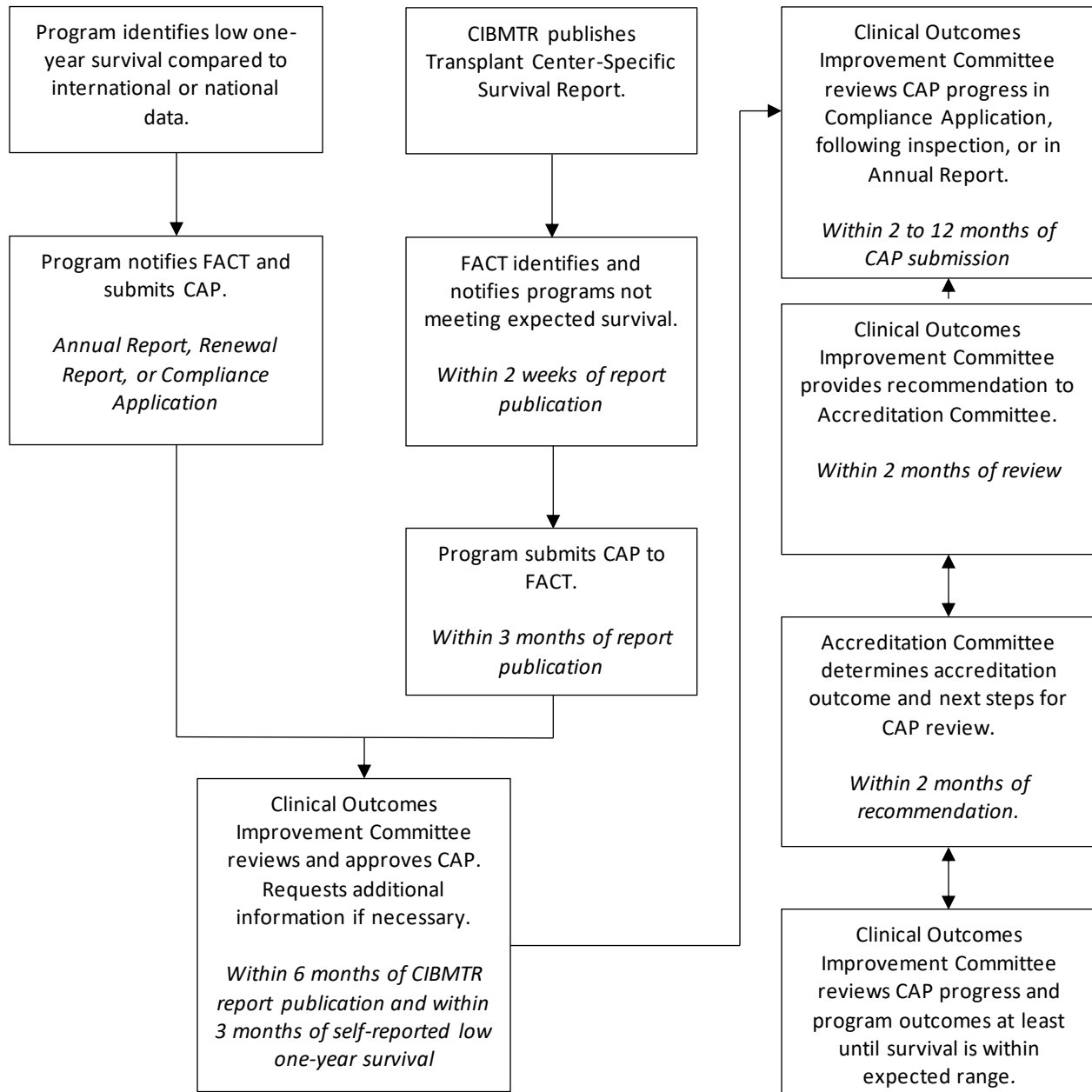
Approved by (date):

Heather Conway (Quality Manager) (20/December/2022), Linda Miller (Chief Operating Officer) (20/December/2022), Phyllis Warkentin (Chief Medical Officer) (20/December/2022)

Appendix A: FACT Process for Reviewing Corrective Action Plans

- 1) Required for Autologous-only programs and programs outside the U.S.**
2) Optional for any program

Required for Allogeneic programs within the U.S.



Appendix B: CAP Determinations

Adequacy of Corrective Action Plan	Accreditation Status and Next Steps
The CAP is satisfactory. No additional information is required at this time. Corrective actions have been implemented and risk-adjusted survival meets the expected range or internal audit data show improvement and survival, as applicable.	The program is accredited. The program will continue to update FACT of its one-year survival compared to the CIBMTR report or other data, as applicable, on an annual basis.
The CAP is satisfactory and has been implemented. Due to recent implementation, no further information is required at this time. No follow up data are yet available.	The program is accredited. Internal data must be submitted to FACT with annual reports or sooner as directed by the Clinical Outcomes Improvement Committee. If one-year survival does not improve, the program must submit a reassessment and revised CAP based on that assessment. The program is accredited contingent on continued timely submission at the direction of the Clinical Outcomes Improvement Committee.
The CAP is satisfactory. Due to the date of approval of the CAP, the CAP has not been implemented. No follow up data are yet available.	The program will submit updates on implementation of corrective actions and internal data to FACT with reports to FACT annually or sooner as directed by the Clinical Outcomes Improvement Committee. If one-year survival does not improve, the program must submit a reassessment and revised CAP based on that assessment. The program is accredited contingent on continued timely submission at the direction of the Clinical Outcomes Improvement Committee.
The CAP has been submitted; however, it is not completely satisfactory. The Clinical Outcomes Improvement Committee requires additional information prior to approving the CAP.	The program must submit this information within timelines requested by the Clinical Outcomes Improvement Committee. The program maintains accreditation throughout the process, contingent on timely and appropriate responses.
The CAP does not meet required guidelines.	The program must submit a revised CAP that meets the guidelines within the timeframes required of the accreditation process or sooner as directed by the Clinical Outcomes Improvement Committee. The program is at risk of accreditation lapse if appropriate responses are not submitted in a timely manner.
The program has not submitted timely, adequate, and accurate responses to the committee or has not demonstrated sufficient ability or effort to evaluate one-year survival and potential corrective actions.	The program may undergo a focused reinspection. The program's FACT accreditation will be on probation until the program has demonstrated satisfactory correction of this deficiency. If not satisfactory, the program's FACT accreditation may be suspended in accordance with Suspension or Termination of Accreditation , ACC.6.1.005.