 <p>FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY AT THE UNIVERSITY OF NEBRASKA MEDICAL CENTER Policies and Procedures</p>	<b>Policy</b>	Document #: ACC.6.1.007 Revision: 0 Approval Date: 11/07/2019 Page 1 of 5 Effective Date: 11/8/2019
<b>Clinical Outcomes Corrective Action Plan Policy</b>		

## 1.0 Purpose

This policy establishes guidelines for compliance with the *FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration* requirements of achieving one-year survival within or above the expected range when compared to national or international outcome data and related submission of corrective action plans (CAPs).

## 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 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 (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, (in press). Integration of publicly reported center outcomes into standards and accreditation: The FACT model. *Biology of Blood and Marrow Transplantation*, doi: 10.1016/j.bbmt.2019.06.035  
<https://www.ncbi.nlm.nih.gov/pubmed/31284070>

## 5.0 Definitions and Abbreviations – NA

## 6.0 Policy

- 6.1 Compliance with Standard B4.7.5.1 is required to maintain FACT accreditation in good standing. Compliance is documented by one of the following:
  - 6.1.1 A program meets the expected outcomes for one-year survival.
  - 6.1.2 A program that does not meet the expected outcomes for on-year survival must implement a CAP that meets FACT requirements and submit the CAP to FACT.
    - 6.1.2.1 Allogeneic transplant programs must submit a CAP when one-year survival does not meet the expected range as reported by the annual CIBMTR Transplant Center-Specific Survival Report.
    - 6.1.2.2 Autologous-only transplant programs or transplant programs outside of the United States must submit a CAP when it identifies low one-year survival compared to national or international data.
- 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 notifying, submitting, and reviewing CAPs is outlined in Appendix A, *FACT Process for Reviewing Corrective Action Plans*.
  - 6.2.2 Potential findings are outlined in Appendix B, *CAP Determinations*.
  - 6.2.3 The Clinical Outcomes Improvement Committee reviews the CAP and interacts directly with the Clinical Programs during the years there is not an on-site FACT inspection.
- 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 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 annual or renewal reporting, or as otherwise directed by the 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 Clinical Outcomes Improvement 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. Demonstrate a measurable outcome improvement, or, if outcomes do not improve, a reassessment of root causes and appropriate corrective actions based on the reassessment.

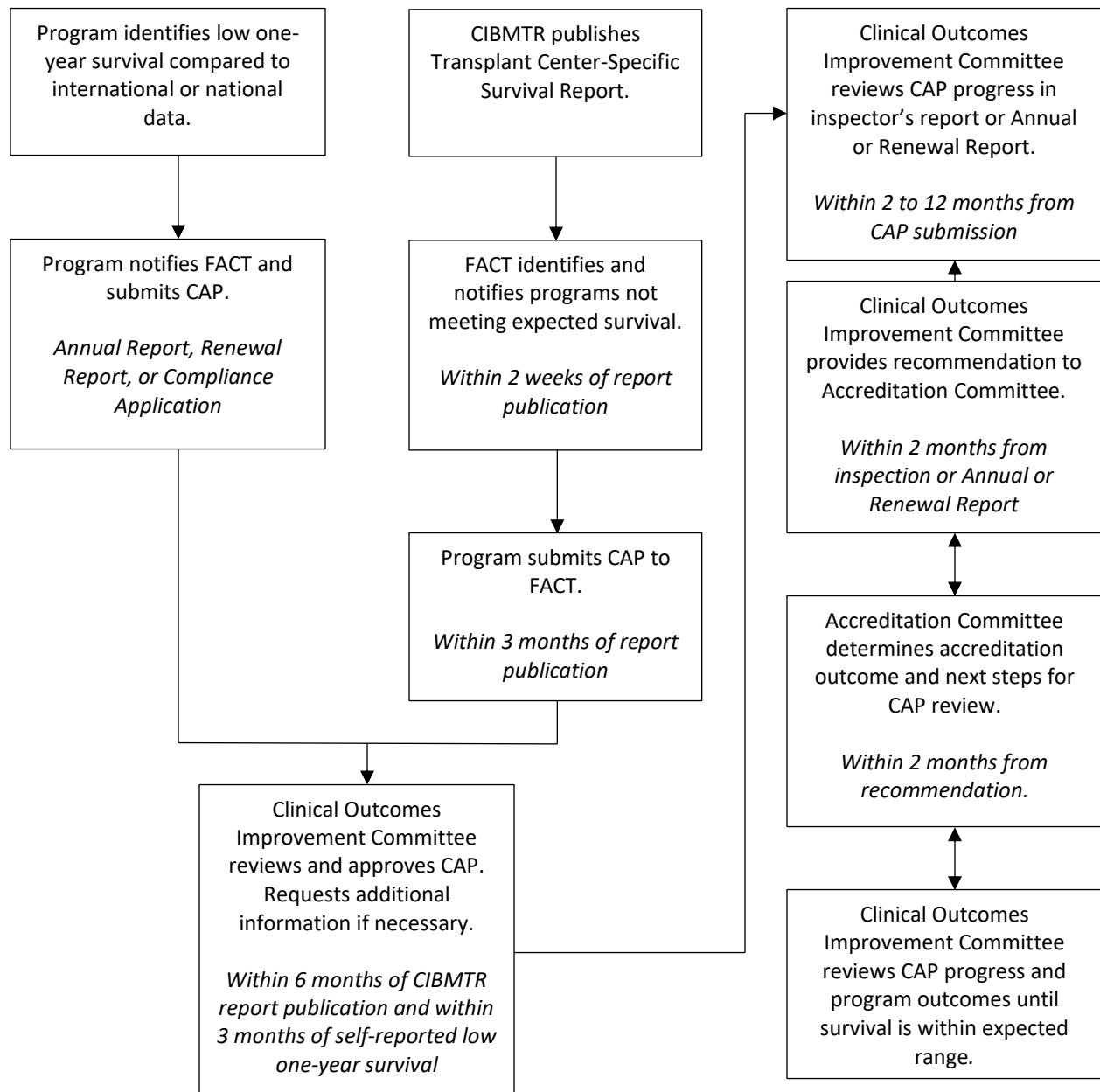
**Approved by (date):**

Heather Conway (Quality Manager) (11/07/2020), Linda Miller (CEO) (11/7/2020), Phyllis I. Warkentin (CMO) (11/7/2020)

## 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 internal audit data show improvement and survival.	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.
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 demonstrate continued improvement in one-year survival at least annually throughout the accreditation process. If one-year survival does not improve, the program must submit a reassessment and revised corrective action plan 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. The program is at risk of accreditation lapse if appropriate responses are not submitted in a timely manner.
The program has not demonstrated sufficient ability or effort to evaluate one-year survival and potential corrective actions.	The program must undergo a focused reinspection. The program's FACT accreditation may be suspended until the focused reinspection has demonstrated satisfactory correction of this deficiency.