

**DUKE****DOCUMENT NUMBER:** COMM-QA-039 JA3**DOCUMENT TITLE:**

QSU Audit Schedule Transplant Programs - STCL

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QSU AUDIT SCHEDULE
TRANSPLANT PROGRAMS/STCL

Program	System/Process Audit (As Applicable)	Frequency
Stem Cell Laboratory (STCL)	<ul style="list-style-type: none"> • Personnel/Training • Facilities • Environmental Monitoring • Equipment Management • Inventory Control/Supply Management • Document Control/Records Management • Process Management and Control • Product Release • Event Management • Quality Improvement • Donor/Recipient/Processing Files • Management of Cellular Therapy Products with Positive Microbial Cultures 	Annually
	<ul style="list-style-type: none"> • External Facility Documentation 	Per COMM-QA-002
Adult Blood and Marrow Transplant (ABMT) Apheresis	<ul style="list-style-type: none"> • Personnel/Training • Facilities • Equipment Management • Inventory Control/Supply Management • Document Control/Records Management • Process Management and Control • Event Management • Quality Improvement • TED Forms/Accuracy of Clinical Data • Donor Screening Testing including: <ul style="list-style-type: none"> ○ Interim assessment of donor suitability prior to the start of the collection procedure ○ Donor eligibility determination prior to the start of the collection procedure • Chemotherapy Records and Prescription Ordering System Against the Protocol • IEC Therapy Safety Endpoints and Toxicity Management 	Annually
	<ul style="list-style-type: none"> • External Facility Documentation 	Per COMM-QA-002

Program	System/Process Audit (As Applicable)	Frequency
Pediatric Blood and Marrow Transplant (PBMT) Apheresis	<ul style="list-style-type: none"> • Personnel/Training • Facilities • Equipment Management • Inventory Control/Supply Management • Document Control/Records Management • Process Management and Control • Event Management • Quality Improvement • TED Forms/Accuracy of Clinical Data • Donor Screening Testing including: <ul style="list-style-type: none"> ○ Interim assessment of donor suitability prior to the start of the collection procedure ○ Donor eligibility determination prior to the start of the collection procedure • Chemotherapy Records and Prescription Ordering System Against the Protocol • IEC Therapy Safety Endpoints and Toxicity Management 	Annually
	<ul style="list-style-type: none"> • External Facility Documentation 	Per COMM-QA-002

Signature Manifest**Document Number:** COMM-QA-039 JA3**Revision:** 04**Title:** QSU Audit Schedule Transplant Programs - STCL**Effective Date:** 24 Jan 2024

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COMM-QA-039 JA3 QSU Audit Schedule Transplant Programs - STCL**Author**

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Document Release

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