

STEM CELL LABORATORY (STCL)



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DOCUMENT NUMBER: STCL-TRN-001 FRM4			
DOCUMENT TITLE:			
Stem Cell Laboratory Medical Director Competer	Stem Cell Laboratory Medical Director Competency Checklist		
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STEM CELL LABORATORY MEDICAL DIRECTOR COMPETENCY CHECKLIST

Staff Member's N	ame				·····
☐ Annual Assessment	☐ Othe	er:			_
TRAINING ELEMENT ASSESSMENT PERIOD:	- NA indicate	c in box indicat es task is not ap es are not accep	plicable	mpletion of ta	šk
ASSESSIVIENT FERIOD;	1 st	2 nd	3 rd	4 th	5 th
NOTE: SOURCE DOCUMENTATION MUST BE AVAILABLE FOR REVIEW FOR EACH OF THE FIVE (5) PROCEDURE PERFORMED / SUPERVISED ANNUALLY	Perform / Supervision Date	Perform / Supervision Date	Perform / Supervision Date	Perform / Supervision Date	Perform / Supervision Date
NOTE: For annual assessment, Processing Medical Director is required to perform or supervise a minimum of five (5) cellular therapy processing procedures per year within each accreditation cycle. Check (V) all applicable procedures performed/supervised during period					
1. STCL-PROC-002 Processing of ABO Incompatible					
Cellular Products					
2. STCL-PROC-007 Peripheral Blood Progenitor Cell –			****		
HPC Apheresis- Concentration and Preparation for					
Cryopreservation					
3. STCL-PROC-021 Thawing of PBPCs or Bone Marrow					
for Direct Administration					
4. STCL-PROC-025 Cryopreservation of Back Up Cells					
from Original UCB Reinfusion			ĺ		
5. STCL-PROC-028 Standard Peripheral Stem Cell				**	
Processing and Preparation for Infusion or					
Cryopreservation.					
6. STCL-PROC-042 UCB Processing Using the SePAX2 S-	****	******		7	
100 Cell Processing System with UCB-HES Protocol					
7. STCL-PROC-044 CBU Processing via Manual Method			***		***************************************
8. STCL-PROC-045 Cryopreservation and Storage of CBU					
9. STCL-PROC-046 Processing of Bone Marrow using the		-			
SePAX 2 RM Instrument	İ				
10. STCL-SOP-028 Procedure for Manually Thawing					
UCBUs Frozen in Two Compartment Bags using					
Dextran-Albumin Solution					
11. STCL-SOP-028 JA2 Dextran Albumin Thawing Vials					
and Small Cryobags			İ		
12. STCL-SOP-028 JA3 Thawing Human-CT-derived			***		·
Mesenchymal Stem Cells (MSCs) for Infusion					
13. STCL-SOP-048 Procedure for Thawing Bone Marrow				1-1111	
and PBPCs using Dextran-Albumin Solution					
Initials, Study ID and Date: My signature and dates certify					
that I have performed or supervised the cellular product processing	Ì				
procedures selected from the list above.					
STCL Processing Facility Medical Director's Signat	– ure		Date		

STCL-TRN-001 FRM4 STCL Medical Director Competency Assessment Durham, NC

Signature Manifest

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Title: Stem Cell Laboratory Medical Director Competency Checklist

All dates and times are in Eastern Time.

STCL-TRN-001 FRM4 Stem Cell Laboratory Medical Director Competency Checklist

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Document Release

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