Title: Technical Release Criteria Checklist Form (NCBH)

Atrium Health Form

Patient Name			Patient MR#	
Donor Name/NMDP#			**Donor MR#**	
ITEMS TO VERIFY	**YES**	**NO**	**Instructions**	**Comments**
The following items can make the product Nonconforming.				
Patient name on Physician Order Form matches label?			If NO and cannot be resolved, product is Nonconforming.	
MR# on Physician Order Form matches label?			If NO and cannot be resolved, product is Nonconforming.	
Infectious Disease Markers have been performed in a specified time range: For HPC,A or HPC,M up to 30 days before or 7 days after collection. For T cells, up to 7 days before or after collection.			If NO, product is Nonconforming.	
HIV antibody; Must be Resulted and Nonreactive			If NO and/or Reactive (pos),product is Nonconforming.	
HIV NAT; Must be Resulted and Nonreactive			If NO and/or Reactive (pos), product is Nonconforming.	
HCV antibody;Must be Resulted and Nonreactive			If NO and/or Reactive (pos),product is Nonconforming.	
HCV NAT; Must be Resulted and Nonreactive			If NO and/or Reactive (pos),product is Nonconforming.	
HBV Surface antigen; Must be Resulted and Nonreactive			If NO and/or Reactive (pos),product is Nonconforming.	
HBV Core antibody; Must be Resulted and Nonreactive			If NO and/or Reactive (pos), product is Nonconforming.	
HBV NAT; Must be Resulted and Nonreactive			If NO and/or Reactive (pos),product is Nonconforming.	
HTLV I/II antibody; Must be Resulted and Nonreactive			If NO and/or Reactive (pos), product is Nonconforming.	
Syphilis; Must be Resulted and Nonreactive			If NO and/or Reactive (pos), product is Nonconforming.	
WNV; Must be Nonreactive			If Reactive (positive), product is Nonconforming. NMDP is exempt from performing until day of collection. If NMDP product, note in Comments.	NMDP Product: YES NO
Chagas antibody; Must be Resulted and Nonreactive			If NO and/or Reactive (pos), product is Nonconforming.	
Bacterial detection testing; Must be Negative			If Positive, product is Nonconforming.	All cultures must be negative at <24 hours. Cultures will be carried out to 5 days.
Other Product Attributes:				
Held at room temperature 8 hours or less?			Product conforming up to 8 hours. Product Nonconforming if at RT >8 hours.	Time at Room Temp:
mL of incompatible RBC ≤20mL?			**OK if ≤20mL RBC. If >20mL of RBC, product is Nonconforming.**	List mL of RBC:
Statement of eligibility, including name and address of facility determining eligibility			If NO, or INCOMPLETE list reason donor is ineligible in Comments.	European Donor:_____ Tattoo within 1 year:_____ Other:_____
Container Intact?			If NO, product is Nonconforming.	
Other			Describe in Comments	

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The following items cannot make the product Nonconforming.				
Correct Product label verified by 2nd technologist?			If NO, have management, or medical director verify product labeling.	
Process worksheet complete and without blanks?			Mononuclear cell count and CD3+ values may not be available at time of product release - This is OK.	
Process worksheet verified by 2nd technologist?			If NO, have management, or medical director verify processing worksheet.	
Are mismatched transfusion requirements in the blood bank computer system?			If NO, notify management to enter in computer system before product release.	
Flow results with printed report in file?			If NO, print Flow results from lab computer system.	
Reagents and materials used for processing are:				
In the dating period?			If NO and cannot be resolved, Consult medical director.	
Lot numbers recorded?			If NO, record lot numbers on Reagent and Disposable Log.	
Donor Eligibility/Compatibility with Recipient: ALLO DONORS ONLY. Enter N/A for AUTO DONORS.				
ABO and Rh compatibility			If NO, list ABOs and product processing in Comments	Patient ABO/Rh: Pt Ab Screen: Donor ABO/Rh: Donor Ab Screen:
HLA compatibility			If NO, print HLA type for patient file.	
Statement that communicable disease testing was performed by a CMS certified laboratory			If NO, list reason lab is not CMS certified in Comments	
Product:				
Cell dose in range:				
HPC: At least 2x10e6 CD34/kg pt. wt.?			If NO, list cell dose in Comments. Complete QA and inform medical director/infusing physician	
Marrow: At least 2x10e8 nucleated cells/kg pt. wt.?			If NO, list cell dose in Comments. Complete QA and inform medical director/infusing physician	
DLI: At least 5x10e6 CD3/kg pt. wt.?			If NO, list cell dose in Comments. Complete QA and inform medical director/infusing physician	
CAR-T Cells: Therapeutic dose?			If NO, list cell dose in Comments. Complete QA and inform medical director/infusing physician	
Other Product Attributes:				
Product ≤ 48 hours from time of collection?			If NO, list product collection location, date/time in Comments Product will have Gram Stain	Collection Location: Expiration Time:
Other			Describe in Comments	

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The following items cannot make the product Nonconforming.				
Infectious Disease Markers				
CMV antibody; Should be resulted and final			OK if NO. Note IgM+ in Comments. Regardless of results, product is conforming for EU products.	
HAV antibody; Should be resulted and final			OK if NO. Note IgM+ in Comments. Regardless of results, product is conforming for EU products.	
HSV 1/2 antibody; Should be resulted and final			OK if NO. Note IgM+ in Comments. Regardless of results, product is conforming for EU products.	
EBV; Should be resulted and final			OK if NO. Note IgM+ in Comments. Regardless of results, product is conforming for EU products.	
VZV antibody; Should be resulted and final			OK if NO. Note IgM+ in Comments. Regardless of results, product is conforming for EU products.	
Toxoplasmosis antibody; Should be resulted and final			OK if NO. Note IgM+ in Comments. Regardless of results, product is conforming for EU products.	
Medical order to issue product was received?			If NO, request Physician Order form from coordinators before issue.	
Process deviations?			If YES, list in Comments	
Quality exceptions?			If YES, complete QA report and list in Comments	
Determine Technical Release Status (Mark One):				
Product is Conforming. Forward this checklist to laboratory medical director for signature.				
Product is Nonconforming. Laboratory medical director and attending physician must be notified AND release signed and returned to SCTCT lab PRIOR to transplant.			**By signing below Attending Physician acknowledges:** *That this product is considered nonconforming for the reason listed above and that the safety and efficacy of this product may be affected. The potential risk from this product is outweighed by the benefits associated with transplantation of this product from this donor. In other words, there is no comparable product and the patient is at increased risk of morbidity/mortality if the product is not infused. I have reviewed the summary of records and elect to receive the product for infusion.*	
Signatures:				
Technologist Completing Release Information				**Date:**
Laboratory Medical Director				**Date:**
Attending Physician (Only for Nonconforming Products)				**Date:**