9.2 Apheresis Tracking Log

Protocol #: _____

Subject #:_____

Product ISBT DIN#:_____

Collection facility: _____

Date of Apheresis:_____

Apheresis start time:_____ end time:_____

Was the apheresis interrupted due to an adverse event or other reason? (y/n):_____

Apheresis Interruption comments:

Final product volume(mL):_____ Actual total blood volume processed (mL)_____

Concurrent plasma volume (mL):_____

Comments:

Subject Pre and Day of Apheresis Peripheral Testing

Subject #: _____
Pre Apheresis Date:_____ Time:_____

Test Type	Results
	Pre Apheresis
CD3+ CD4+ CD8-%	
CD3+ CD4+ CD8- absolute	
CD3+ CD8+ CD4- absolute	
CD3+ CD8+ CD4- %	
CD4/CD8 ratio	
CD3+ CD4+ CD8+ %	
CD3+ CD4+ CD8+ absolute	
CD3+ CD4- CD8- %	
CD3+ CD4- CD8- absolute	

Comments:

Completed by:
Signature:_____
Initials:_____
Date:_____

Subject #: _____

Day of Apheresis Peripheral Blood Testing: Date:_____

Test Type	**Results**		**Critical (Circle or mark appropriate answer)**
	Pre Apheresis	**Post Apheresis**	
HCT %			Y N (<20%)
WBC ($10^{\wedge 3}$/uL)			Y N
Hgb(g/dL)			Y N
Platelets ($10^{\wedge 3}$/uL)			Y N (<20x$10^{\wedge 3}$/uL)
IDM			☐ Complete and Non-reactive ☐ Complete with reactive test(s) – see included results

Comments:

Completed by:
Signature:_____
Initials:_____
Date:_____

Apheresis Product Analysis:

Subject #: _____ Product DIN#_____

Apheresis Product Testing date:_____ Time:_____

Test Type	Results
HCT %	
WBC ($10^{\wedge 3}$/uL)	
Hgb(g/dL)	
Platelets ($10^{\wedge 3}$/uL)	
Gram Stain	
CD3+ %	
CD3+ Total in product	

Comments:

Completed by:

Signature:_____

Initials:_____

Date:_____

Apheresis Product Testing:

Subject #: _____ Product DIN#_____

Date:_____ Time:_____

Test Type	**Results**
CD3+ absolute (cell/l)	
CD3+ CD4+ CD8-%	
CD3+ CD4+ CD8- absolute	
CD3+ CD8+ CD4- absolute	
CD3+ CD8+ CD4- %	
CD4/CD8 ratio	
CD3+ CD4+ CD8+ %	
CD3+ CD4+ CD8+ absolute	
CD3+ CD4- CD8- %	
CD3+ CD4- CD8- absolute	

Comments:

Completed by:
Signature:_____

Initials:_____

Date:_____

9.3 Cell Product Receipt Form

Cryopreserved Product Receipt Checklist

PRIOR TO SHIPMENT OF PRODUCT				TECH
DIN(s) Assigned: _____				
Subject Name		Sending Institution		
Subject MRN		Product Local ID # (s)		
Subject DOB				
Courier		Scheduled Date/Time of Delivery		

AT PRODUCT RECEIPT					TECH
Canister(s) placed in vapor phase to cool					
Date Received:	Time Received:	Temp. Device ID:	Thermocouple ID:	Omega Temp. of Shipper °C:	
Shipper ID:		Data logger ID:		Data Logger Temp °C:	
Data Logger in alarm at arrival?				□ Yes □ No	
Product Acceptable- Not thawed/cracked				□ Yes □ No	
Sufficient samples provided for required genetic testing or cryovials provided for viability testing?				□ Yes □ No	
Location of product(s) storage and bag type documented below				□ Yes □ No	
Are all required documents present, including but not limited to: · Circular of Information · IDM Test Results · Final Declaration of Eligibility · Microbial Results · Product Insert (Processing Report/Summary)				□ Yes □ No	
Product Receipt form completed and scanned and emailed to sending institution				□ NA	
Investigational Protocol Coordinator notified of product receipt and required follow-up □ NA Person Notified: _____ Notified Via: _____ Date: _____					

RECEIPT OF PRODUCTS							
Local Product ID #	**Product ID #(DIN)**	**Bag Type**	**Frame**	**Canister**	**Freezer #**	**Cryovial Location**	**Tech**

Comments: _____

_____

_____

9.4 Product Label Examples

Apheresis Collection Label Example

Final CAR T-Cell Product Label Example

Dispensing label:

Maintain thawed IP at room/ambient temperature and light conditions.

Avoid direct sunlight exposure

Expiry* ___/___/___ ____ ____

Preferred format dd/mon/yyyy HH MM

Expiration time is 6 hours after the IP infusion bag has been thawed

9.5 Chain of Custody Log

CHAIN OF CUSTODY

Directions: Use this form to document the COC for a product if the collection facility or administrating site does not already have a specific form. Document time using the 24-hour clock. If courier signature cannot be obtained during drop off, N/A the corresponding signature box.

Product ID:		Study ID, if applicable:	

Collection Facility to Courier				
Collection Center				
Representative:	Signature:	Date:	Time:	Time Zone:
Courier				
Representative:	Signature:	Date:	Time:	Time Zone:
Courier to IU Cell Immunotherapy and Transduction				
Courier				
Representative:	Signature:	Date:	Time:	Time Zone:
Cell Immunotherapy and Transduction				
Representative:	Signature:	Date:	Time:	Time Zone:
IU Cell Immunotherapy and Transduction to Courier				
Cell Immunotherapy and Transduction				
Representative:	Signature:	Date:	Time:	Time Zone:
Courier				
Representative:	Signature:	Date:	Time:	Time Zone:
Courier to Administrating Site				
Courier				
Representative:	Signature:	Date:	Time:	Time Zone:
Administrating Site*				
Representative:	Signature:	Date:	Time:	Time Zone:

Infusion Site Representative: Please scan and e-mail the completed form on the day of receipt to dakkenn@iu.edu and CITLabIU@iu.edu.

Use the enclosed shipping waybill to return the dry shipper as soon as possible

Reviewed By (signature/date):	
QA Review (signature/date):	

9.6 Infusion Documentation Log

Infusion Documentation Log

Date of infusion:	**Name of personnel completing this form:**
Infusion start time:	**Infusion end time:**
Total infusion time (minutes):	

Initials:	**Date form completed:**