INDIANA UNIVERSITY
MELVIN AND BREN SIMON
COMPREHENSIVE CANCER CENTER

CONFIDENTIAL

CD4 CAR Cell Therapy Manual

CTO-IUSCCC-ICG122-101

A Phase I, Multicenter Study of CD4- directed chimeric antigen receptor engineered T-cells (CD4CAR) in patients with Relapsed or Refractory CD4+ Lymphoid Hematological Malignancies

And

CTO-IUSCCC-0840

CD4CAR T CELL THERAPY FOR CMML

And

CTO-IUSCCC-0851

CD4CAR T CELL THERAPY FOR AML

Sponsor-Investigator

Huda Salman, MD, PhD

Coordinating Center:

Indiana University Melvin and Bren Simon Comprehensive Cancer Center

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Table of Contents

1.0 GENERAL INFORMATION

1.1 Overview of Manual

This Cell Therapy Manual complements protocols CTO-IUSCCC-ICG122-101, CTO-IUSCCC-0840, and CTO-IUSCCC-0851 by providing additional information on how the cell therapy aspects of the study should be conducted to ensure compliance with the protocol, the principles of Good Clinical Practice (GCP), the International Conference on Harmonization (ICH) guidelines, and Indiana University Melvin and Bren Simon Comprehensive Cancer Center (IUSCCC) Clinical Trials Office's (CTO) requirements.

All individuals who are responsible for conducting Protocols CTO-IUSCCC-ICG122-101, CTO-IUSCCC-0840, and CTO-IUSCCC-0851 should refer to this manual in conjunction with the protocol.

1.2 Study Roles and Responsibilities

- Huda Salman, MD, PhD is the Sponsor-Investigator of these clinical studies and is responsible for providing coverage to evaluate eligibility questions, answering safety related questions, and reviewing serious adverse event (SAE) reports.
- The Indiana University Melvin and Bren Simon Comprehensive Cancer Center (IUSCCC) Clinical Trials Office (CTO) is responsible for clinical trial management, serious adverse event (SAE) management and sponsor-investigator communications.
- The IUSCCC's Multicenter Project Manager (MPM) is the participating sites' first line of communication. The MPM is responsible for clinical trial oversight, receipt and evaluation of SAE reports from participating study sites, ensuring protocol compliance to ICH-GCP, local and federal regulations.
- The respective local institutional review boards (IRBs) (or single IRB as applicable) will be used during this study to grant approval for research conduct at each center.
- This study will be conducted in accordance with the protocol and all local and federal regulations including ICH-GCP, and IUSCCC standard operating procedures.

1.3 Contact Information

Study Representative	Contact
Sponsor- Investigator	Huda Salman, MD, PhD Phone: (317) 278-9504 E-mail: hsalman@iu.edu
Multicenter Project Manager	Sheri Jones Phone: (317) 278-5165 E-mail: srlipps@iu.edu Fax: (317) 274-8022 Or Jennifer Lehman Phone: (317) 274-0972 Email: jgeck@iu.edu Fax: (317) 274-8022
Cell Immunotherapy and Transduction (GMP Facility) Contacts	Christina Vaughan, MS (CIT Manager) Phone: (317) 274-5728 E-mail: crobakow@iu.edu Emily Hopewell, PhD (Director of Cell and Gene Therapy Manufacturing) Phone: (317) 278-1109 Email: emlhope@iu.edu
Apheresis and Cellular Therapy Laboratory Contacts (IUSCCC only)	Dave Schwering (Cellular Therapy Manager) Phone: 317-944-2558 Email: dschwering@IUHealth.org Sakiah Smith-Rich (Apheresis Manager) Email: SSmith20@iuhealth.org

2.0 STUDY SUPPLIES AND MATERIALS

Each institution will be responsible for procuring supplies necessary for administration of IP unless otherwise specified.

2.1 Investigational Product (IP): CD4CAR T-cells

How Supplied: One to two 10-30mL cryobags

2.2 Supplies for Infusion of IP

- Refer to section 9.2.2 in the protocol for a complete list

2.3 Labeling

- Collection and product labels must be ISBT 128 compliant

3.0 APHERESIS

Communication along with completion of the Request for Manufacturing form (section 9.8) must be sent to the MPM at the Coordinating Center at least 14 days in advance that an Apheresis collection has scheduled; so that they can coordinate with the manufacturing facilities to determine where the cells will be shipped. Apheresis collection should be performed according to site standard operating procedures with the goal to collect approximately $5X10^8$ total nucleated cells to manufacture CD4CAR T-Cells from a single leukapheresis. Lower yields are acceptable. See section 9.4 of this manual for required testing of leukapheresis collections. ***Briefly, testing includes CBC, leukemia/lymphoma flow (if required), and T-cell subset analysis***.

Apheresis centers are required to make arrangements to have the required testing performed and results attached to the product via a tie tag for CBC. The T-cell subset test results should be provided to the manufacturing center once completed. Samples should be obtained from a sampling bulb on the apheresis disposable or attached tubing. DO NOT spike or open the apheresis bag to obtain a sample.

Note: The Apheresis tracking log (section 9.4) must accompany the apheresis product to the manufacturing site.

Refer to section 8.3.1.2 of the protocol for more information. If collecting optional blood samples for future research at time of apheresis, this sample must be collected before apheresis begins.

3.1 Transfer of Apheresis Product

IUSCCC: Apheresis product will be received by the Cellular Therapy lab and then transferred to the Cellular Immunotherapy and Transduction lab for manufacturing within one hour of collection end time. If more time is required, please place into appropriate temperature monitored storage (2-8 °C) until the time of transfer occurs. Apheresis product needs to arrive at manufacturing facility within 24 hours of collection.

Participating Sites: Apheresis product will be shipped to the Indiana University Cell Immunotherapy and Transduction Facility. Apheresis product must be transferred and placed into 2-8 °C shipper within one hour (60 minutes) of collection end time. If more time is required, please place into appropriate temperature monitored storage (2-8 °C range) until the product is placed in the 2-8^{o}C shipper. Confirm no temperature excursions once the product has reached the 2-8^{o}C range. Shipment needs to arrive at manufacturing facility within 24 hours of collection. Contact the multicenter project manager if these conditions cannot be met.

Complete the applicable Chain of Custody form (or institutional equivalent) in appendix 9.7.

4.0 MANUFACTURING OF IP

Manufacturing of IP will take place at the Indiana University Cell Immunotherapy and Transduction Facility.

5.0 CRYOPRESERVATION AND PACKAGING OF IP

Refer to section 8.3.1.3 in the protocol for more information.

At the end of cell culture, the cells are cryopreserved in infusible cryomedia and will be shipped to the site following completion of release testing. Cell products will be stored at or below -150^{o} C in a vapor nitrogen freezer.

6.0 SHIPMENT OF IP

IP (CD4CAR T cells) is manufactured after a subject is enrolled and has completed apheresis. The cell product is expected to be ready for release approximately 4 weeks after start of manufacturing.

IUSCCC: After completion of manufacturing of the CD4CAR cellular product, one bag will be transferred to the Cellular Therapy Lab for temporary storage until the time of infusion. The certificate of analysis form and chain of custody document will accompany IP.

Participating sites: After completion of manufacturing of the CD4CAR cellular product, one bag of CD4CAR T cells will be shipped directly to the site via a temperature monitored liquid nitrogen cryoshipper. All necessary documentation will accompany the shipment. Additional bags of subject specific CD4CAR T cells will remain at the processing facility as back up infusions. The certificate of analysis form and chain of custody document will accompany IP.

The LN2 Dry Shipper will be charged and temperature monitored per institution standard procedures. **NOTE:** CD4CAR T Cells shall be transported at or below -150 degrees Celsius in the vapor phase of liquid nitrogen (dry shipper).

Appropriate shipping and warning labels are applied to the outer shipping container. When IP is transported the temperature of the shipper is monitored continuously.

Refer to section 8.3.3 of the protocol for more information.

Complete the Chain of Custody form (or institutional equivalent) in appendix 9.7.

6.1 RECEIPT OF IP

IP will be delivered per section 8.3.4 of the protocol. A chain of custody document will be maintained to document movement of the cells in the facility.

Study staff should verify that the shipment contains all items noted in the shipment inventory included in the shipper. Any damaged or unusable study drug in a shipment should be documented in the study files and reported to the coordinating center immediately.

The following procedures should be followed upon receipt of IP:

- Ensure that the lid of the shipper is sealed upon arrival. Remove the lid (if necessary) and confirm the temperature of the container and record on Cryopreserved Product Receipt Checklist (Appendix 9.5)

- Carefully remove the product from the dry shipper and open the cassette to inspect the bag. Ensure labels are appropriately attached and the bag itself is intact. Record the products condition on Cryopreserved Product Receipt Checklist (Appendix 9.5)

- Ensure that all the required documents were sent along with the product

- The receiving personnel should print and sign their name on Cryopreserved Product Receipt Checklist (Appendix 9.5) and follow the emailing instructions on the form

6.2 STORAGE OF IP

Once received by the research site, investigational product must be stored according to the conditions on the label, in a secure location with limited access.

After logging the cells in the research site facility, the bag(s) containing CART-4-transduced T cells will be stored in the research site's Stem Cell Therapy Lab (or equivalent), in a monitored ≤-150°C freezer. Infusion bags will be stored in the freezer until needed. CART-4-transduced T cells will be delivered and stored in accordance with each site's policy.

7.0 IP PREPARATION AND ADMINISTRATION INSTRUCTIONS

7.1 IP Preparation

Refer to section 8.3.5 of the protocol for detailed information.

Complete Appendix 9.3 Investigational Product Thaw Record (or site equivalent), and 9.9 Day of Infusion Documentation.

If the CD4CAR T cell product appears to have a damaged or leaking bag, or otherwise appears to be compromised, it should not be infused, and should be returned to the site's cell processing facility. The site coordinator should contact the multicenter project manager immediately to facilitate shipment of back up bag to site. The CD4CAR T cell product expires 6 hours after thaw.

IP preparation must occur based on the time of scheduled administration to account for the 6 hours expiry of the post thawed IP. IP preparation will be performed by appropriately trained staff under the responsibility of the site's Principal Investigator.

7.2 IP Dispensing Labels

A fillable tie tag will be attached to the bag for the thawed IP and will include at a minimum the following information for the IP Infusion Bag post thaw:

1. Thawed date and time:
    a. Preferred format: dd / MON / yyyy HH:MM*

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

7.3 IP Administration

Refer to section 9.2.2 in the protocol for detailed instructions.

Prior to Infusion:

On the day of the infusion, the RN will assemble supplies for infusion:

- One 1 liter bag of Plasma-Lyte A injection pH 7.4, one BD SmartSite Gravity set or equivalent, and one secondary admin set with bag hanger (Note: secondary admin set is not applicable if gravity set has dual spikes)
- Vital signs cycling every 15 minutes

Each research site will follow their institutional policy for infusion of CAR-T products. Below is an example of how the process **could** be performed:

- Prime one spike and line of tubing with approx. 500ml of Plasmalyte A. This will connect to central line on subject. Clamp after primed.
- Remainder of tubing should already be primed with Plasmalyte A. Spike CAR T- cell bag with the non-primed side of tubing and prime with CART-T cells to drip chamber.
  - ***Note: Be careful to not touch the spike as this will contaminate the CAR T bag.***
- Infuse the entire contents of the CAR-T cell bag by gravity. Gently agitate the CAR-T cell bag during infusion to prevent cell clumping.

Post Infusion: *Flush (Rinse)*

- Vital signs, including temperature, respiratory rate, pulse, blood pressure and oxygen saturation will be taken before infusion, every 15 minutes throughout infusion, at completion of infusion and every 15 minutes thereafter for at least one hour until vital signs are satisfactory and stable (may be up to 6 hours post infusion)
- Following infusion, rinse the bag and infuse that rinse into the recipient ,repeat backflush process by adding 20 mL of Plasmalyte A into the the IP bag. Leave the bag inverted and seal above the bag so that the bag can be aseptically removed.

8.0 DESTRUCTION OR RETURN OF INVESTIGATIONAL PRODUCT

Refer to section 8.3.6 in the protocol for further information.

Used or partially used IP and/or IP bags will be destroyed onsite according to site policies and the status should be documented on an On-site IP Inventory Log. IP is considered used once it is thawed.

8.1 IP Return

Refer to section 8.3.6 in the protocol for further information.

8.2 UNDISTRIBUTED IP

Refer to section 8.3.6 in the protocol for further information.

9.0 APPENDICES

Appendix 9.1 CD4CAR T Cell Shipping Memo
Appendix 9.2 CryoShipper Shipping Transport Label
Appendix 9.3 IP Thaw Record
Appendix 9.4 Apheresis Tracking Log
Appendix 9.5 Cell Product Receipt Form
Appendix 9.6 Product Label examples
Appendix 9.7 Chain of Custody Log

9.1 Shipping Memo Form

Shipping facility:

_____

_____

_____

_____

Phone:

Contact Person:_____

Product Shipment

Record*Shipper handling instructions:*

Human Cells for Administration
Handle with Care
Do Not X-Ray
Do Not Irradiate

Product DIN	Product Type	Volume (mL)	Collection Date	Packaged Time
Total units = ___				

Product Information
Subject Name: _____
Subject MRN: _____
Subject Date of Birth: _____
Subject Number: _____
Subject IBST#:_____

Product Type (Select One):

☐**T-Cells, Apheresis**
□Label affixed to product container
□ISBT # is present
□Expiration date and time
□ subject #, DOB
□Volume
□Product placed in secondary sealed plastic “zip lock” bag
□Anticoagulant and volume (if applicable)

☐**MNC, Apheresis**
□Product container is intact
□Collection date and time
□Blood type or N/A
□Product Type

Packaged by:_____

Package verification by:_____

Receiving Facility

Facility _____ **Address**_____
Contact Person _____**Phone #** ( ) _____
City, State, Zip_____

Received by:_____
Received time: _____
Received date: _____
Temp at receipt: _____
Product Temperature excursion (after reaching 2-8°C**) :** ☐**yes** ☐**no** ***If yes contact MPM immediately**
☐ **Data logger and completed form scanned and emailed to MPM within 2 business days of receipt**

****Note: Please use in tandem with 9.5 Cell Product Receipt Form, if applicable, and 9.7 Chain of Custody Log**

9.2 CryoShipper Shipping Transport Label Example

Shipper Transport Label Example

No matter the shipping method used, the following information must be included on all labels.

Complete information. The distribution time and time zone may be written by hand using black indelible ink. Print full sheet label(s) using qualified label stock and printer. Cut along the dotted line below and attach label to the exterior of the Dry Shipper and the shipping case (if applicable)

✂_ _

Shipper ID or SN:	
Distribution Date:	
Distribution Time:	**Time Zone: EST / EDT/CST/CDT/MST/MDT/PST/PDT (circle one)**
Handling Instructions	**HUMAN CELLS FOR ADMINISTRATION** **HANDLE WITH CARE!** ***DO NOT X-RAY*** ***DO NOT IRRADIATE***
WARNING	**Extremely Cold Contents < -150°C (-238 °F)** **May Cause Severe Frostbite**
Shipping Facility Address	Institution Facility Name Street Address Room Number City State Zip
Shipping Facility Contact	Name: Phone#: Email:
Receiving Facility Address	Institution Facility Name Street Address Room Number City State Zip
Receiving Facility Contact	Name Phone# Email:

DO NOT OPEN THIS SHIPPING CONTAINER UNLESS YOU ARE THE DESIGNATED RECEIVING FACILITY CONTACT OR AUTHORIZED DESIGNEE

Product Transport Label

Qualified Shipping Container ID:	
Distribution Date:	
Distribution Time:	**Time Zone: EST / EDT/CST/CDT/MST/MDT/PST/PDT (circle one)**

MEDICAL SPECIMEN
HANDLE WITH CARE!
DO NOT X-RAY
DO NOT IRRADIATE

Transport Temperature	☐ Ambient ☐ 4° C
Shipping Facility Address	Institution Facility Name Street Address Room Number City State Zip
Shipping Facility Contact	Name: Phone#: Email:
Receiving Facility Address	Institution Facility Name Street Address Room Number City State Zip
Receiving Facility Contact	Name Phone# Email:

9.3 IP Thaw Record

INVESTIGATIONAL PRODUCT THAW RECORD

Study Site:_____

Infusion Date:
Product DIN#:
Subject Study ID:
Water Bath Manufacturer:
Water Bath Serial Number:
Last Calibration Date:
Next Calibration Date:
Temperature Set Point: 37°C

PREPARATION

Location of preparation:_____

Disinfect water bath per institution policy Initials:_____ Date:_____

Fill with 0.9% normal saline or sterile water Initials:_____ Date:_____

0.9% Normal Saline Lot#: ☐N/A	Expiration Date: ☐N/A
Sterile Water Lot#: ☐N/A	Expiration Date: ☐N/A

THAW

Location of Thaw:_____

Record Water Bath Temperature immediately prior to thaw: _____°C

Start Time of Thaw:_____(HH:MM) Time Zone:_____

End Time of Thaw:_____(HH:MM) Time Zone:_____

Product thawed by:_____(print name)

Initials: _____ Date:_____

Return completed form to Site Coordinator

9.4 Apheresis Tracking Log

Subject Name: _____ 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:

Apheresis Tracking Log completed by: Initials: _____ Date:_____

Note: Samples may be sent to the Cell Immunotherapy and Transduction Facility for the T-cell subset processing with collection.

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)			
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)	
CD3+ %	
CD3+ Total in product	

Any results that are not yet available by time of shipment, please note in the results section and then provide the results as soon as available to the IUSCCC Multicenter Project Manager.

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:_____

Apheresis Product Testing: **leukemia/lymphoma flow (*as needed*)**

Subject #: _____ Product DIN#_____

Date:_____ Time:_____

Test Type	**Results**
leukemia/lymphoma immunophenotyping (for malignant cell presence)	

Comments:

Completed by:
Signature:_____

Initials:_____

Date:_____

Note: Sample must be submitted as 'Apheresis product for CAR-T procedure'

9.5 Cell Product Receipt Form

Cryopreserved Product Receipt Checklist

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

Instructions: Below to be completed by the receiving institution. Please have the Technician initial and date information completed.

AT PRODUCT RECEIPT				TECH	Date
Receiving Institution:					
Canister(s) placed in vapor phase to cool					
Date Received:	Time Received:				
Shipper ID:	Data logger ID:	Data Logger Temp °C:			
Data Logger in alarm at arrival?			□ Yes □ No		
Product Acceptable- Not thawed/cracked			□ Yes □ No		
Location of product(s) storage and bag type documented below			□ Yes □ No		
Are all required documents present, including but not limited to: · Certificate of Analysis (COA) · Shipping Memo · Chain of Custody			□ Yes □ No		
Product Receipt form completed and scanned and emailed to sending institution □ NA					
Institutional BMT Transplant Nursing Coordinator notified of product receipt and required follow-up □ NA Person Notified: _____ Notified Via: _____ Date: _____					

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

Comments: _____

_____

_____

9.6 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

9.7 Chain of Custody Log

CHAIN OF CUSTODY

Directions: If not IUH Cellular Therapy, document collection center/cell therapy facility institution in Other. Document time using the 24-hour clock. Courier and scheduled delivery date/time is not applicable between IUH Cell Therapy and IU Cell Immunotherapy and Transduction. Please ensure all fields are completed.

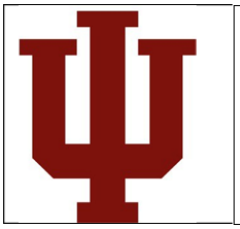
Product ID:		Subject ID	

Collection Facility/Cell Therapy Facility to IU Cell Immunotherapy and Transduction Facility				
Collection Center/Cell Therapy Facility : ☐ IU Health Cellular Therapy ☐ Other:				
Collection Center/Cell Therapy Representative:	Signature:	Date:	Time:	Time Zone:
Courier: _____ Scheduled Pick Up Date/Time: _____ Tech Initials: _____				
Cell Immunotherapy and Transduction				
CIT Representative:	Signature:	Date:	Time:	Time Zone:
IU Cell Immunotherapy and Transduction to Cell Therapy Facility				
Cell Immunotherapy and Transduction				
CIT Representative:	Signature:	Date:	Time:	Time Zone:
Courier: _____ Scheduled Pick Up Date/Time: _____ Tech Initials: _____				
Collection Center/Cell Therapy Facility : ☐ IU Health Cellular Therapy ☐ Other:				
Cell Therapy Representative:	Signature:	Date:	Time:	Time Zone:
Cell Therapy Facility to infusion Site				
Cell Therapy Representative:	Signature:	Date:	Time:	Time Zone:
Document Infusion Site (if different institution than Cell Therapy Facility):				
Infusion Site Representative:	Signature:	Date:	Time:	Time Zone:

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

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

9.8 CIT Request for Manufacturing Autologous Product



Indiana University School of Medicine

Cell and Gene Therapy Manufacturing

Cell Immunotherapy and Transduction (CIT) Facility
550 N. University Blvd., UH3453A
Indianapolis, IN 46202

Request for Manufacturing Autologous Product

Orders	
IU Protocol/Name	
Principal Investigator	
Dose Assigned	

Patient Information (Name, MRN, DOB not required if recipient label is present)		
Name (Last, First, MI)		Label
MRN		
DOB		
Study ID, if applicable		
Weight (kg)		

Manufacturing Information	
Manufacturer	☒CIT ☐Other: _____
Final Product Temperature Requirements	☐Fresh, store at 4°C until administration ☒Frozen, store at <-150°C until administration
Final Product Cell Packaging	☒Cryo bag ☐Transfer bag ☐Syringe ☐Other: _____
Extra dose information, if applicable:	☐Fresh, in syringe ☒Frozen, in cryobag

Manufacturing Authorization	
I hereby authorize the applicable manufacturer to manufacture cell product for patient administration as described above per IND and facility SOP guidelines.	
Target Collection Date	
Requesting Physician (Sign and Date)	

Please scan and email completed form to emlhope@iu.edu and crobakow@iu.edu.

9.9 Day of Infusion Documentation

INDIANA UNIVERSITY
MELVIN AND BREN SIMON
COMPREHENSIVE CANCER CENTER

Day of Infusion Documentation

Directions: Use this for to document the information regarding the infusion of the CD4CAR product.

Date of infusion:	**Name of personnel completing this form:**	
Dose level:		
Infusion start time:	**Infusion end time:**	
Total infusion time (minutes):		
Was the infusion interrupted for any reason?	☐ **yes**	☐**No**
If yes, comment:		
Were there any infusion reactions?	☐ **yes**	☐**No**
If yes, time of reaction:		
Treatment required for infusion reactions?	☐ **yes**	☐**No**
If yes, treatment given for infusion reaction:		
If yes, time of treatment given for infusion reaction:		
Comments:		

Initials:	**Date form completed:**

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