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| Image result for IUSCCCCONFIDENTIALCell Therapy Manual CTO-IUSCCC-ICG122-101A Phase I, Multicenter Study of CD4- directed chimeric antigen receptor engineered T-cells (CD4CAR) in patients with Relapsed or Refractory CD4+ Lymphoid Hematological MalignanciesSponsor-Investigator Huda Salman, MD**Coordinating Center:** Indiana University Melvin and Bren Simon Comprehensive Cancer Center

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| **Version** | **Date** |
| Initial Issue | 12.1.2022 |

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# GENERAL INFORMATION

## Overview of Manual

This Cell Therapy Manual complements protocol CTO-IUSCCC-ICG122-101 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 Protocol CTO-IUSCCC-ICG122-101 should refer to this manual in conjunction with the protocol.

## Study Roles and Responsibilities

* Huda Salman, MD is the Sponsor-Investigator of this clinical study 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) 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.

## Contact Information

| **Study Representative** | **Contact** |
| --- | --- |
| **Sponsor- Investigator** | Huda Salman, MDTelephone: (317) 278-9504E-mail: hsalman@iu.edu  |
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| **Director of Cell and Gene Therapy Manufacturing** | Emily Hopewell, PhDPhone: (317) 278-1109E-mail: emlhope@iu.edu  |
| **Director Cell Immunotherapy and Transduction (GMP Facility)** | Vicki GravesPhone: (317) 274-5732E-mail: vlgraves@iu.edu vlgraves@iu.edu  |
| **Manager of Apheresis and Cellular Therapy Laboratory**  | Dave Schwering317-944-2558 Officedschwering@IUHealth.org |

# STUDY SUPPLIES AND MATERIALS

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

## Investigational Product (IP): CD4CAR T-cells

How Supplied: One to two 10-30mL cryobags

## Supplies for Infusion of IP

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

## Labeling

* Collection and product labels must be ISBT 128 compliant

# APHERESIS

Communication 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.

Refer to section 8.3.1.2 of the protocol for more information.

## 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 (or shipping if Louisville will be 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 or the University of Louisville Dunbar CAR T-Cell GMP 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) until the time of shipment occurs. 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 Chain of Custody form (or institutional equivalent) in appendix 10.8.

# MANUFACTURING OF IP

Manufacturing of IP will take place at either the Indiana University Cell Immunotherapy and Transduction Facility or the University of Louisville Dunbar CART-Cell GMP Facility.

# 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 -150o C in a vapor nitrogen freezer.

# 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 apheresis.

**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:**  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 10.8.

## 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 10.6)
* Remove the product from the plastic bag and visually inspect it. Ensure there are no clots and the bag itself is intact. Record the products condition on Cryopreserved Product Receipt Checklist (Appendix 10.6)
* 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 10.6) and following the emailing instructions on the form

## 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.

# IP PREPARATION AND ADMINISTRATION INSTRUCTIONS

## IP Preparation

Refer to section 8.3.5 of the protocol for detailed information.

Complete Appendix 10.3 Investigational Product Thaw Record (or site equivalent).

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.

## IP Dispensing Labels

A label generated for the thawed IP will include the following at a minimum the following information for the IP Infusion Bag post thaw:

1. Maintain thawed IP at room/ambient temperature and light conditions. Avoid direct sunlight exposure

2. Expiry\*:

a. Preferred format: dd / MON / yyyy HH:MM

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

## IP Administration

Refer to section 9.2.2 in the protocol for detailed instructions.

Below is an example of how the process **could** be performed:

* Open BD Alaris Pump Infusion Burette Set (or equivalent), unwind, and hang on IV pole to prepare to prime set with Plasma-Lyte A. Close all clamps. This will be the primary IV tubing.
* Open secondary admin set. Spike Plasma-Lyte A 1L bag with secondary admin set, ensuring tubing clamp is in the closed position. Attach to luer lock on Buretrol cylinder of primary IV set.
* Prime the Buretol of the BD Alaris Pump Infusion Burette Set (or equivalent) with Plasma- Lyte. Make sure no air bubbles are in the primed tubing.
* The Buretrol cylinder should have approximately 15 cc before CAR T cell products are added.
* Re-clamp the tubing once the priming is complete.
* Spike CAR T- cell bag with the BD Alaris Pump Infusion Burette Set (or equivalent) and add CAR T-cell content to Buretrol cylinder. Clamp tubing from CAR T cell bag to cylinder once contents are infused.
* CAR T-cells are to be diluted with a volume of Plasma-Lyte A, take note to not over-dilute the cells which can cause cellular destruction. The dilution of approximately 15 cc is necessary to increase the volume of the infusion to meet the 20-30 minutes infusion time desired for the first several patients as per protocol.

Note:

1. The CAR T-cell volume is estimated at about 10 cc, though may change with increasing doses and manufacturing facility
* This reflects a total of approximately 25 cc in the Buretrol cylinder. Program Alaris pump accordingly to accomplish infusion in 20-30 minutes.

**Post Infusion:** *Flush (Rinse) and culture*

* Swab additive port of Plasma-Lyte A bag on IV pole with alcohol swab. Puncture diaphragm of port with syringe and needle
* Pull approximately 10 cc Plasma-Lyte A
* Change needle to a vented dispensing pin, or equivalent
* Spike access port of empty CAR T-cell bag with dispensing pin and inject syringe of approximately 10 cc Plasma-Lyte A.
* Massage CAR T- cell bag gently to dispense Plasma-Lyte A
* Unclamp slide clamp and infuse volume into Buretrol cylinder
* Add more Plasma-Lyte A to Buretrol cylinder for an approximate flush of 30 cc.
* Infuse this flush at fast rate, approximately 2 minutes.
* 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 and flush, do NOT throw away CAR T-cell bag, Plasma-Lyte A bag or tubing. Send the bags and tubing to the clinical lab for culture.

# POST-INFUSION CULTURE

Refer to 9.2.3 in the protocol for more information.

1. Following infusion, obtain culture specimen from CAR-T cell bag using aseptic technique and send to site’s institutional clinical lab for processing.
2. Label culture bottles with “CAR-T” and the unique product number, and a barcoded patient ID label

# 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.

## IP Return

Refer to section 8.3.6 in the protocol for further information.

## UNDISTRIBUTED IP

Refer to section 8.3.6 in the protocol for further information.

#  APPENDICES

Appendix 10.1 CD4CAR T Cell Shipping Memo

Appendix 10.2 CryoShipper Shipping Transport Label

Appendix 10.3 IP Thaw Record

Appendix 10.4 Apheresis Tracking Log

Appendix 10.5 Cell Product Receipt Form

Appendix 10.6 Product Label examples

Appendix 10.7 Chain of Custody Log

## Shipping Memo Form

***Shipping facility:* Product Shipment Record *Shipper handling instructions:***

***(If you are a participating site, please update*** Human Cells for Administration

***with your address)*** Handle with Care

Apheresis and Cellular Therapy Laboratory Do Not X-Ray

550 N. University Blvd. Do Not Irradiate

Indianapolis, IN 46202

Phone: (317) 944-2558

Contact Person:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**Product Information**

**Subject Name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Subject MRN:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Subject Date of Birth:­­­­­­­­­­­­­­­ ­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Subject Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Product Type (Select One):**

**□T-Cells, Apheresis □MNC, Apheresis**

□Label affixed to product container □Product container is intact

□ISBT # is present □Collection date and time

□Expiration date and time □Blood type or N/A

□ subject #, DOB □Product Type

□Volume

□Product placed in secondary sealed plastic “zip lock” bag

□Anticoagulant and volume (if applicable)

Packaged by:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Package verification by:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Received by:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Received time:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Received date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Temp at receipt:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Data logger alarm:** [ ] **yes** [ ] **no \*If yes contact MPM immediately**

[ ]  **Data logger scanned and emailed to MPM within 24hours of receipt**

**\*\*Note: Please use in tandem with 10.8 Chain of Custody Log**

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##

## CryoShipper Shipping Transport Label

|  |
| --- |
| ***LN2 Dry Shipper Transport Label***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 AddressRoom NumberCity State Zip |
| Shipping Facility Contact | Name:Phone#:Email: |
| Receiving Facility Address | Institution Facility Name Street AddressRoom NumberCity 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 🞎 4o C |
| Shipping Facility Address | Institution Facility Name Street AddressRoom NumberCity State Zip |
| Shipping Facility Contact | Name:Phone#:Email: |
| Receiving Facility Address | Institution Facility Name Street AddressRoom NumberCity State Zip |
| Receiving Facility Contact | Name Phone# Email: |

## 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: 37oC  |

**PREPARATION**

Disinfect water bath per institution policy Initials:

Fill with 0.9% normal saline or sterile water Initials:

|  |  |
| --- | --- |
| 0.9% Normal Saline Lot#: 🞎N/A  | Expiration Date: 🞎N/A |
| Sterile Water Lot#: 🞎N/A | Expiration Date: 🞎N/A |

**THAW**

Record Water Bath Temperature immediately prior to thaw: oC

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

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

Product thawed by: Initials

Return completed form to Site Coordinator

##  Apheresis Tracking Log

Subject Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Subject #:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Subject ISBT#:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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):\_\_\_\_\_\_\_\_\_ Gram staining result on apheresis product:\_\_\_\_\_\_\_\_\_\_

Comments:

**Subject Pre and Post Apheresis Peripheral Testing**

Pre Apheresis Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Time:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |
| --- | --- | --- |
| **Test Type** | **Results** | **Critical (Circle Yes or No)** |
| **Pre Apheresis** | **Post Apheresis** |
| HCT % |  |  | Y N (<20%) |
| WBC (10^3/uL) |  |  | Y N |
| Hgb(g/dL) |  |  | Y N |
| Platelets (10^3/uL) |  |  | Y N (<20x10^3/uL) |
| CD3+ absolute (cell/l) |  |  | NA |
| 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:

**Analysis:**

Apheresis Product Testing date:\_\_\_\_\_\_\_\_\_\_\_ Time:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |
| --- | --- |
| **Test Type** | **Results** |
| HCT % |  |
| WBC (10^3/uL) |  |
| Hgb(g/dL) |  |
| Platelets (10^3/uL) |  |
| 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:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## 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 |  |
| Institutional BMT Transplant Nursing Coordinator notified of product receipt and required follow-up 🗆 NAPerson Notified: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Notified Via: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_ |  |

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

## Product Label Examples





**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*** |

## Chain of Custody Log

**CHAIN OF CUSTODY**

**APHERESIS PRODUCT**

|  |  |
| --- | --- |
| Product DIN: | Study # or Acrostic:🞎 N/A |
| **Shipper to Courier** |
| Shipper: | Signature: | Date: | Time: | Time Zone:🞎 EST/EDT🞎CST/CDT🞎MST/MDT🞎PST/PDT  |
| Shipper Representative: |
|  Courier:  | Signature: | Date: | Time: | Time Zone:🞎 EST/EDT🞎CST/CDT🞎MST/MDT🞎PST/PDT  |
| Courier Representative: |
| **Courier to Manufacturer** |
| Courier: | Signature: | Date: | Time: | Time Zone:🞎 EST/EDT🞎CST/CDT🞎MST/MDT🞎PST/PDT  |
| Courier Representative: |
| Manufacturer: | Signature: | Date: | Time: | Time Zone:🞎 EST/EDT🞎CST/CDT🞎MST/MDT🞎PST/PDT  |
| Manufacturer Representative: |
| **Please use 24 hour clock and record the time in the time zone in which you are currently located** |
| **Manufacturer Representative:** Please scan and e-mail this completed form along with the temperature monitoring file (pdf) to srlipps@iu.edu  |

**CHAIN OF CUSTODY**

**INVESTIGATIONAL PRODUCT**

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| **Manufacturer to Courier** |
| Manufacturer: | Signature: | Date: | Time: | Time Zone:🞎 EST/EDT🞎CST/CDT🞎MST/MDT🞎PST/PDT  |
| Manufacturer Representative: |
| Courier: | Signature: | Date: | Time: | Time Zone:🞎 EST/EDT🞎CST/CDT🞎MST/MDT🞎PST/PDT  |
| Courier Representative: |
| **Courier to Site of Study Product Administration** |
| Courier: | Signature: | Date: | Time: | Time Zone:🞎 EST/EDT🞎CST/CDT🞎MST/MDT🞎PST/PDT  |
| Courier Representative: |
| Site of Cellular Product Administration:  | Signature: | Date: | Time: | Time Zone:🞎 EST/EDT🞎CST/CDT🞎MST/MDT🞎PST/PDT  |
| Representative: |
| **Please use 24 hour clock and record the time in the time zone in which you are currently located** |
| **Infusion Site Representative**: Please scan and e-mail the completed form on the day of receipt to srlipps@iu.edu.**Use the enclosed shipping waybill to return the dry shipper as soon as possible** |