MiSLE Investigational Product Training

Shipping, Receipt and Infusion
February 2019 Update

- Scheduling an infusion
- Receiving a shipment
- Inspecting the investigational product (IP)
- Preparing the IP for infusion
- Contact information

Agenda

Scheduling an Infusion

- Study Center obtains consent and proceeds with screening assessment
  - 28-day time clock begins (infusion must be completed within 28 days of consent)
  - Labs drawn on same day as consent
  - Lab results reported as soon as possible
  - If lab results fail, redraw labs and report
- Study Center contacts MUSC to reserve tentative infusion date
  - Email Angela Robinson robia@musc.edu for possible infusion dates
  - Infusion dates should occur Tuesday-Thursday
- Study Center completes data entry and initiates randomization process
  - Once patient meets eligibility requirements, data entry must be completed on the WebDCU website
  - Randomize the study subject
- CCT confirms infusion date and begins investigational product preparation
  - After randomization, CCT will receive automated notification from the WebDCU
  - CCT will confirm the infusion date with the study center
  - Confirm the Subject ID, CMV status and most recent patient weight (kg)

Receiving a Shipment

- Tracking information will be sent one day prior to the infusion date
- Shipment will contain:

Exterior box will have two strips of Purple Tape, for easy recognition.

- Certificate of Analysis
- Checklist
- Product Transfer Form
- Instructions for data logger
- Shipper pack out

IP is wrapped in absorbent pad and placed within the Ziploc bag.

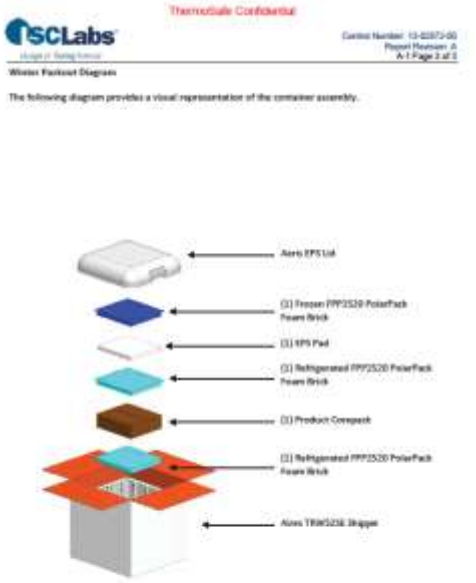
Temperature monitor is wrapped with the IP inside the absorbent pad.

Labeled infusion bag will arrive inside the amber bag with IV tubing cover.

Shipment Pack Out

There are two different “pack out” options: winter and summer.

Winter pack out

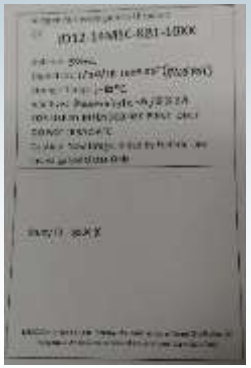


Summer pack out

Inspecting the Product

- Designated site manager should inspect the IP to verify bag integrity, labeling, etc.
- To maintain the blind, IP should be mixed by rocking and massaging the bag immediately *prior to* removal from the amber bag
  - NOTE: Mixing the product should always be done prior to removal from the amber bag in order to reduce the chance of breaking the blind.

Inspecting the Product



Example of Label

The following should be confirmed:

i. Acceptable product appearance (no damage)

ii. Product container integrity (no leaking)

iii. Acceptable product volume (confirm on COA)

iv. Product expiration date/time (confirm expiration not exceeded)

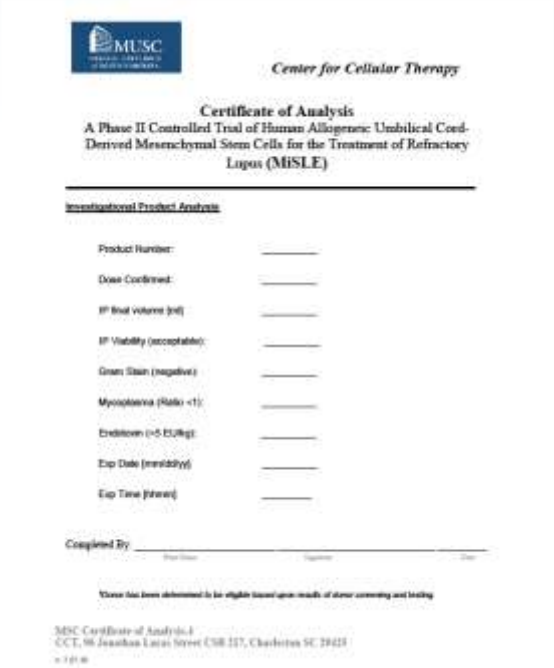
v. Acceptable storage conditions and transport container temp (1-6°C)

vi. Recipient identity and product type on the product label (study ID and patient ID matched)

Inspecting the Product: Forms

You will receive:

1) Certificate of Analysis



MUSC

Center for Cellular Therapy

Certificate of Analysis

A Phase II Controlled Trial of Human Allogeneic Umbilical Cord-Derived Mesenchymal Stem Cells for the Treatment of Refractory Lupus (MiSLE)

Investigational Product Analysis

Product Number: _____

Dose Confirmed: _____

IP final volume (ml): _____

IP Viability (acceptable): _____

Gram Stain (negative): _____

Mycoplasma (Ratio <1): _____

Endotoxin (<5 EU/kg): _____

Exp Date (mm/dd/yy): _____

Exp Time (hhmm): _____

Completed By: _____

2) Product Transfer Form

MUSC

Center for Cellular Therapy

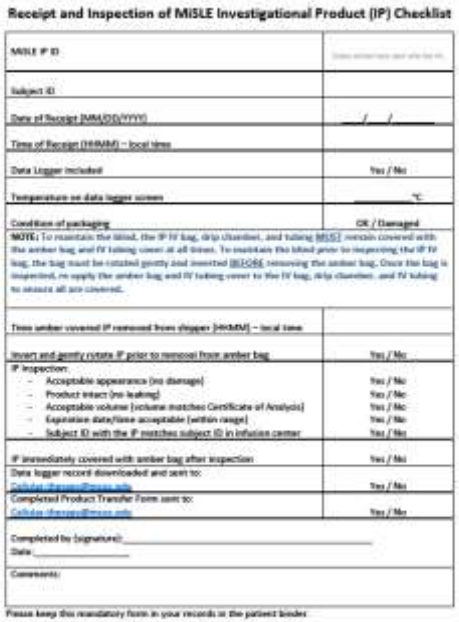
Product Transfer Form

For Shipping Facility Use Only

For Receiving Facility Use Only

Please Fax completed copy of this form to: 843-792-9621 Or Scan to cellular-therapy@musc.edu

3) IP Checklist



Receipt and Inspection of MiSLE Investigational Product (IP) Checklist

MiSLE IP ID	
Subject ID	
Date of Receipt (MM/DD/YYYY)	___/___/_____
Time of Receipt (HHMM) – local time	
Data Logger included	Yes / No
Temperature on data logger screen	_____ °C
Condition of packaging	OK / Damaged
NOTE: To maintain the blind, the IP IV bag, drip chamber, and tubing MUST remain covered with the amber bag and IV tubing cover at all times. To maintain the blind prior to inspecting the IP IV bag, the bag must be rotated gently and inverted BEHIND removing the amber bag. Once the bag is inspected, re-apply the amber bag and IV tubing cover to the IV bag, drip chamber, and IV tubing to ensure all are covered.	
Time amber covered IP removed from shipper (HHMM) – local time	
Invert and gently rotate IP prior to removal from amber bag	Yes / No
IP inspection:	
– Acceptable appearance (no damage)	Yes / No
– Product intact (no leaking)	Yes / No
– Acceptable volume (volume matches Certificate of Analysis)	Yes / No
– Expiration date/time acceptable (within range)	Yes / No
– Subject ID with the IP matches subject ID in infusion center	Yes / No
IP immediately covered with amber bag after inspection	Yes / No
Data logger record downloaded and sent to: cellular-therapy@musc.edu	Yes / No
Completed Product Transfer Form sent to: cellular-therapy@musc.edu	Yes / No
Completed by (signature): _____ Date: _____	
Comments:	

Please keep this mandatory form in your records or the patient binder.

Bottom portion will need to be completed at site by designated IP inspection personnel

Use this form as a guideline or record for receipt if needed by PPD or other agency

Inspecting the Product: Data Logger Instructions

Data Logger instructions will accompany the IP

NOTE: Software must be updated to “MaxiThermal2” in order read the data logger. The previous software version is not compatible and will result an error message.

Instructions for the temperature data logger:

- Record Temperature indicated on screen
- Pull back the black rubber tab from bottom of logger(Fig A & B)
- While holding tab to side place logger into the reader (Fig C)
- Open the MaxiThermal 2 Software
- Read Logger
- Print Summary and Graph

Fig A

Fig B

Fig C

Inspecting the Product: Data Logger Instructions

Step 1.

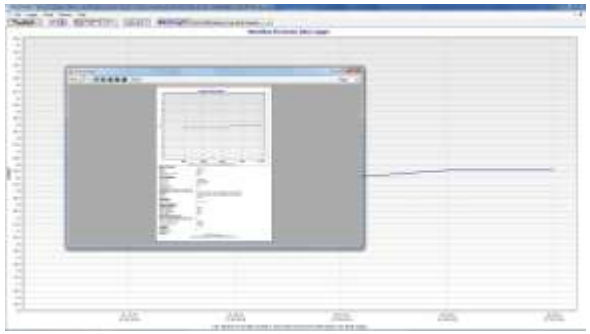
- Load logger on dock and insert USB in computer
- Select “Logger”, “Read Logger”

Step 2.

- Save Information

Step 3.

- Print: Graph & Summary



Step 4.

- Scan results to: cellular-therapy@musc.edu

Inspecting the Product

- After IP inspection, the product should be covered with the amber bag and stored at refrigerated temperatures (1-10°C), either in the shipper or refrigerator (no temperature monitoring required).
- At time of product receipt, email the temperature monitoring data and Product Transfer form to Quality Department at MUSC, cellular-therapy@musc.edu.
- If there are any questions related to the integrity of the IP, contact your site principal investigator
- IP expiration is 48 hours (begins at time of final product preparation prior to shipment).
  - Refer to Certificate of Analysis or Label for expiration date and time, time will be listed as EST and local time in parenthesis if applicable.
- Transfer the IP (infusion bag in amber bag and IV tubing cover) to the infusion center.

Preparing the IP for infusion

- Prime tubing with NS.
  - NOTE: Tubing will vary site-to-site depending on the infusion pump used.

- Pull the amber cover from the bottom of the primed tubing to the drip chamber.

Preparing the IP for infusion

- **Completely** cover the drip chamber with the amber cover.

- Secure the amber cover to the drip chamber with tape.
  - NOTE: To maintain the blind, the drip chamber must be **completely** covered at **all** times!

Preparing the IP for infusion

- Remove the IP from its amber cover/bag just enough to expose the ports. **Do not** uncover the entire IP bag.
- Twist off a port's cap, and use the primed tubing from the NS bag to spike the IP bag.
- Spike the IP bag by pressing firmly with a twisting motion.
- Tilt port upright while spiking to help prevent spillage

Make sure to spike the bag PRIOR to hanging

Preparing the IP for infusion

- Ensure that the IP bag and drip chamber are completely obscured by the amber covers. **You are now ready for IP administration!**

- After the entire volume of the IP bag has been infused, hang a bag of NS and flush with at least 30 mL (enough to clear the IV line of IP). The rate should be the same as that of IP administration.

Contact Information

For scheduling an infusion date and Investigational Product related questions:

Center for Cellular Therapy cellular-therapy@musc.edu

- Tara Duke (Director of Quality Assurance) duket@musc.edu
- Cindy Wang (Lab Operations Manager) wangxi@musc.edu