



- 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 <u>robia@musc.edu</u> 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.



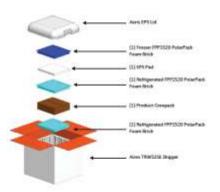
Shipment Pack Out

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

Winter pack out



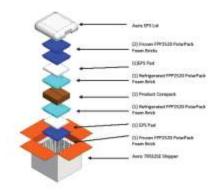
The following diagram provides a visual representation of the committee assembly.





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

2) Product Transfer Form

Product Transfer Form			
fert	inging facility Line Only		
Sharing Parity:	CityStelle		
Fernance Facility	Color News		
Adhes	Oytun		
Personnel Danate Date	Assail Straping Date/Conte-		
Med M.			
Product Fyen: 2 Allogeress Innerspective Prod	Coloropyeessed MCCC (cg)		
SFE Bookers Harrion	Esposos trae		
() tay-Cyngresine	history 2100		
Copyrenewel file learly flat the above liked product have been streeding againsts and other below trapistor and determination for amountable for disolation figuresis.	Dat Meshate 4: 1785. send at the appropriate intravenure is accordance. These products and accompanying scords have be litted line Popper.	en income	
The Cypersons Congress and Congress and Interpretary of the control of the cont	Del Producte (L. 1995) street of the appropriate for personnel accordance. These products and accordancy right scottle files to "Baselfiles Rocket." The function of the distance of (Line). [The solving Society blue Only.	en income	
I To Compression I to C	Distribution & 1700. These products in decompanying scorel from the products and documentarying scorel from the products and documentarying scorel from the products. These products and document (1700. 1100. White Packety Lies Only of products (1700. 1100. These passings Only 1100.	trie .	
To Cupperson Tourness and I have been been graded to be a consistent of the construction of the	Distribution & 1700. These products and accompanying secret free by taken from Foundation of Contracting Secret free by taken from Foundation	tries	
I To Comparison I To Comparison I Comparison	Distributes & LTIC Insert of the appropriate increases in accordance These products and accordance ying accret free in International Contract (1746 - 174	tries	
In the Companion of th	Distribution & LTDC Interest in the government of exceptions of a conditional form and the conditional form of the conditiona	Trible Trible Trible	

Bottom portion will need to be completed at site by designated IP inspection personnel 3) IP Checklist

MALE P.D.	-
Subject 83	
Date of Secret (MACOD/YYY)	-/-
Time of Receipt (HRVM) - local time	
Data Lingger Included	two/Nor
Temperature on data legger screen	
MOTE; To reasonable the Mind, the IP IV has, drip classifier, and taking it the arriver has send if I salming comes at 40 times. To reasonable the behalf a sing, the hair must be establed growthy and invested <u>MEQSE</u> removing the impression, or spaying the sendon hair order from yourse to the IV has, in	ner to requesting the IP II a animal long. Over the los
	to clumber, and N future
Trees without vivored IF removed from shapper (MSMM) - local time.	to classes, and N Library
to advance all and comment. These under covering of command from singular (MCANV) - local time. Invest and gently system of price to remove from antient big.	Tes / No.
to secure off per-chyered.	0
Tree under violented if remained hims shapper (HSMM) - insid time invers and gently ristate if prior to remove the avoid to be inverse and gently ristate if prior to remove the avoid to be inverse and gently ristate if prior to the avoid to be inverse and prior to be avoid in the avoid to be a	Yes / No Yes / No Yes / No Yes / No Yes / No
These surface coverand if remnanced from shapper [MCASAI] — found time. Invest and gently crystals if police to remnance from another beg. F inspection: Acceptable appearance for diseases! F nonther treater for selecting! Acceptable schemic from the control of the control of Analysis (Expension stars/from acceptable (within reage) (Expension stars/from acceptable (within reage) (Expension stars/from acceptable (within reage) (F investigate) covered with unified to grifter inspection Data larger record diseases and acceptable (within acceptable) and acceptable process of diseases and acceptable (F investigate) covered with unified tog other inspection.	Year / Mor Year / Mor Year / Mor Year / Mor Year / Mor
To examine all pin-circles. These surface vicewised if represent from shapper [HMMM] - insul time inversal and gently rivinte. If prior to remove them and/or bag. If improved the proposed proposed them and/or bag. Acceptable appearance (no densign) Acceptable return the selenge Acceptable robuses [rechars basefine] Basef	Tree / Mor Tree / Mor Year / Mor Year / Mor Year / Mor Year / Mor

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



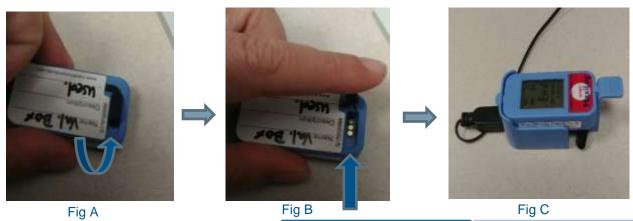
Inspecting the Product: Data Logger Instructions

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



Inspecting the Product: Data Logger Instructions

Step 1.

- Load logger on dock and insert **USB** in computer
- Select "Logger", "Read Logger"



Step 2.

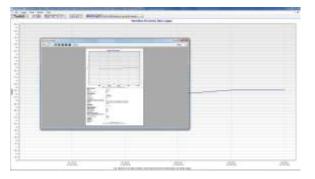
- Save Information



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, cellulartherapy@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.





- 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.





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!

- 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

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) <u>duket@musc.edu</u>
- Cindy Wang (Lab Operations Manager) <u>wangxi@musc.edu</u>

