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# MNC SHIPMENT AND HANDLING HANDBOOK FOR EXTERNAL SITES

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Therapeutic Cell Production Core

<p style="text-align: center;"><b>SEATTLE CHILDREN’S THERAPEUTICS</b>  <b>THERAPEUTIC CELL PRODUCTION CORE</b>  <b>CLINICAL DOCUMENT</b></p>	<p>Document number: TCPC-MNCHandbook  Revision: 08  Effective date: 01/12/2023  Page 2 of 13</p>
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**TABLE OF CONTENTS**

- 1. PURPOSE..... 3**
- 2. TRAINING..... 3**
- 3. DEFINITIONS..... 3**
- 4. MATERIALS ..... 3**
- 5. GENERAL INFORMATION ..... 4**
- 6. SUBJECT IDENTITY VERIFICATION..... 5**
- 7. PACKAGING AND SHIPPING..... 6**
- 8. REVISION HISTORY ..... 12**
- 9. APPENDIX ..... 13**

**1. PURPOSE**

- 1.1. The purpose of this procedure is to define the process for packaging and shipping autologous mononuclear cell (MNC) collections for Seattle Children's clinical trials.

**2. TRAINING**

- 2.1. Prior to initiating a new study at each external Clinical Site, a member of the TCPC team will provide training to the Clinical Site team members on shipping and handling of the MNC product.
- 2.1.1. Training by TCPC will not be required for any subsequent studies if the receipt, shipping and handling procedures are equivalent to any study the Clinical Site may have previously been trained on.

**3. DEFINITIONS**

- 3.1. COI – The process that links a subject's autologous blood product to the subject from the MNC Collection through final product administration to ensure that the right autologous product gets to the right subject for infusion.
- 3.2. MNC – Mononuclear Cell
- 3.3. MRN – Medical record number. Unique identifier assigned by the hospital.
- 3.4. TCPC – Therapeutic Cell Production Core
- 3.5. Whole Blood Processed Volume (WBPV) – The amount of subject whole blood that travels over the collection or inlet pump during the collection procedure.

**4. MATERIALS**

- 4.1. TCPC supplied materials to Clinical Site:
- 4.1.1. Completed Schedule Confirmation Form (SCF)
- 4.1.2. MNC Shipping Container and packaging materials (via Quick)
- 4.1.2.1. Crēdo Cube
- 4.1.2.2. Biohazard Specimen Transport Bag
- 4.1.2.3. Bubble Wrap
- 4.1.2.4. 12 x 12 inch Absorbent Sheet
- 4.1.2.5. TempTale4 USB Temp Logger
- 4.1.2.6. Quick International Bill of Lading

4.1.2.7. Do Not X-Ray Label

4.1.2.8. Exempt Human Specimen Label

**NOTE:** Ensure that shipping container and packaging materials are available. If not, contact TCPC.

## **5. GENERAL INFORMATION**

5.1. **IMPORTANT:** File a copy of all subject-related paperwork (i.e. TCPC Clinical Forms) with the Clinical Subject Study Binder or equivalent.

### **5.2. Chain of Identity**

5.2.1. For TCPC autologous products, COI is maintained by the distinct identification code of the study subject ID. The study subject ID will be maintained through all aspects of the MNC collection, manufacturing, testing, packaging, and transport of product.

5.2.2. Additional COI requirements used by TCPC are:

5.2.2.1. Subject name

5.2.2.2. Date of birth

5.2.2.3. Medical Record Number (MRN)

5.2.3. MNC product must be labelled with all of the above subject COI requirements, typically with a hospital patient identification label. The use of an additional ISBT label is acceptable.

5.3. Follow institutional policy for the following practices:

5.3.1. Safe-handling and personal protection

5.3.2. Aseptic technique

5.3.3. Subject evaluation and care

5.3.4. Venipuncture and Central Venous Access Device (CVAD) use

5.3.5. MNC collection except as specifically called out in this policy

5.3.6. Biohazard disposal

5.3.7. Federal guidelines / policies for biohazardous material packaging

5.4. The MNC product should be packaged for shipment in either the apheresis unit or within the BMT Lab, whichever is applicable to the clinical site.

5.5. Site staff must package the MNC product as soon as possible after completing the collection.

- 5.6. TCPC will schedule courier delivery of the MNC shipping container (Crêdo Cube) at the time specified on the Scheduling Confirmation Form (SCF).
- 5.7. Courier will arrive at the projected time supplied on the SCF with the pre-conditioned Crêdo Cube and wait while Clinical Site staff package the MNC product.
- 5.8. When the MNC Product is packaged, the courier will collect the shipping container and ship to TCPC.
- 5.9. **IMPORTANT:** If projected courier pick up time needs to be rescheduled due to delays, contact TCPC immediately. Delivery of product to TCPC is expected at 7AM the following morning. Delay in shipment and subsequent delivery of product to TCPC may result in a delay of manufacturing.

## 6. SUBJECT IDENTITY VERIFICATION

- 6.1. In the presence of the subject or subject's guardian, perform subject identity verification. Subject Name on the MNC Bag Label should exactly match the method of subject identity verification being performed:
  - 6.1.1. Subject's government issued photo identification, or
  - 6.1.2. Subject's medical institution identification, or
  - 6.1.3. Verbally confirm with the subject or subject's guardian that their identifiers on the MNC Bag Label are accurate.
  - 6.1.4. If there is a discrepancy, DO NOT proceed. Immediately contact TCPC for further guidance.
  - 6.1.5. Verify the following information on the MNC Bag Label exactly matches the information on the SCF:
    - 6.1.5.1. Last Name
    - 6.1.5.2. First Name
    - 6.1.5.3. Middle Name, if applicable
    - 6.1.5.4. Date of Birth
    - 6.1.5.5. Medical Record Number

**NOTE:** Subject Lot # will not be included on the MNC bag label but MUST be included on the MNC Collection Form. Subject Lot Number is to be retrieved from the Medidata Database.
  - 6.1.5.6. If there is a discrepancy, DO NOT proceed. Immediately contact [TCPC@seattlechildrens.org](mailto:TCPC@seattlechildrens.org) for further guidance.

- 6.2. Complete the MNC Collection Form and make a copy to be included in the product shipment.

**NOTE:** When the MNC Collection Form is completed, it is the very first step of the manufacturing process to associate a subject's identifiers with their study subject ID.

- 6.3. File original MNC Collection Form in the clinical subject study binder.  
6.4. Immediately package the MNC product for shipment using the instructions in Section 7.

**NOTE:** The MNC product expires after 48hours from collection end time.

## 7. PACKAGING AND SHIPPING

- 7.1. The apheresis product should be packaged for shipment either at the apheresis unit or within the BMT Lab or equivalent.
- 7.2. Ensure that MNC shipment has been scheduled to be picked up at the apheresis unit or BMTL and delivered to TCPC, and that the Quick Bill of Lading has been generated and 2 copies printed.
- 7.2.1. Each printed copy will consist of an upper section "Copy A" and a lower section "Copy B." Sign in the lower left corner of Copy A as the Shipper with date and time.
- 7.3. Courier will arrive with pre-chilled Crêdo Cube with TempTale4 USB temp logger already recording. Discard paperwork affixed to top of package (**Figure 1**).




**Figure 1 – Crêdo Cube**

- 7.4. Open the Crêdo Cube shipping container and remove the upper lid (**Figure 2**).



Figure 2 - Opened Crēdo Cube

- 7.5. Remove the shipping materials from the inside of the shipping container and verify the following are present:
  - 7.5.1. Bubble wrap
  - 7.5.2. One specimen transport bag
  - 7.5.3. One 12x12inch absorbent sheet
  - 7.5.4. One TempTale4 USB temp logger with sun icon  on unit display (indicating it is recording). If the sun icon is not present, instruct the courier to start the temp logger recording immediately.
- 7.6. Insert the MNC product into the specimen transport bag with the MNC Bag Label facing outward (**Figure 3**).

**NOTE:** MNC Bag Label should be visible and not obstructed. The label should be facing the side of the specimen transport bag without the biohazard symbol, so the label is visible inside the bag.

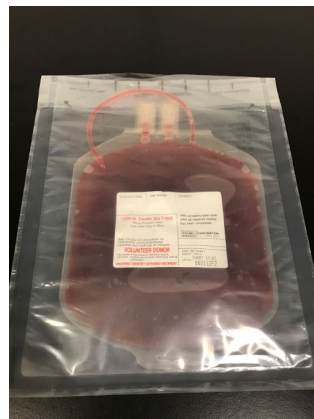
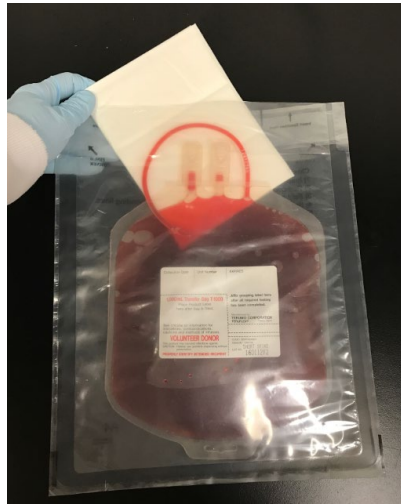


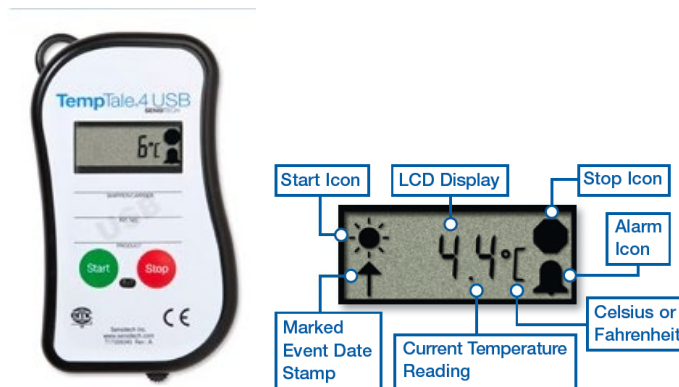
Figure 3 - MNC product in specimen bag

- 7.7. Insert the absorbent sheet into the specimen transport bag, making sure not to obstruct the MNC Bag Label (**Figure 4**). Ensure the MNC product and absorbent sheet are placed inside the specimen transport bag and not in the outer document sleeve.



**Figure 4 - Inserting absorbent sheet**

- 7.8. Expel the air from the specimen transport bag, remove the adhesive backing, and seal the bag.
- 7.9. Insert the temperature data logger in the document pocket of the outside of the specimen transport bag ensuring it does not obstruct the view of the MNC bag label (**Figure 5 and 6**).



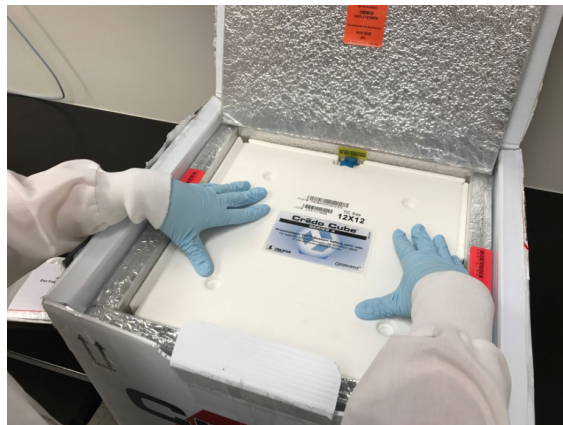
**Figure 5 - Temperature Data Logger and display**





**Figure 6 - Temp logger inserted into the document sleeve**

- 7.10. Remove the top Thermal Isolation Chamber (TIC) panel. Wrap bubble wrap around the MNC Product and place inside the Crêdo Cube compartment.
- 7.11. Replace the top TIC panel and press down firmly (**Figure 7**).



**Figure 7 – Replacing top TIC panel of Crêdo Cube**

- 7.12. Place the upper lid on top of the top TIC panel and press down firmly.
- 7.13. Place a copy of the completed MNC Collection Form on top of the Crêdo Cube upper lid (**Figure 8**).

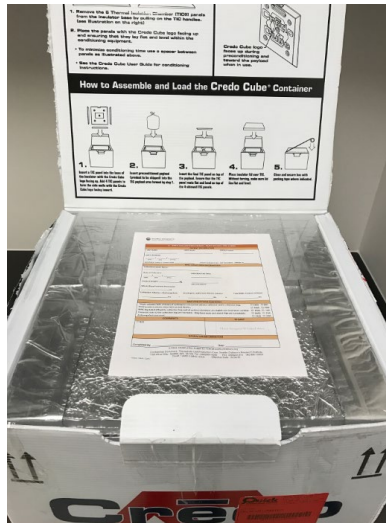


Figure 8 – Crêdo Cube with copy of MNC Collection Form

- 7.14. Close the shipping container and tape shut with shipping tape. Place tamper-evident shipping tape (supplied by TCPC) over regular shipping tape.
- 7.15. Enclose both Quick Bill of Ladings in a document pouch and affix pouch to the top of the package (Figure 9).



Figure 9 – Credo Cube with Quick Bill of Lading affixed

- 7.16. Ensure the following labels are affixed to the exterior of the Crêdo Cube Shipping Container (Figure 10):
  - 7.16.1. TCPC Address Label
  - 7.16.2. Do Not X-Ray
  - 7.16.3. Exempt Human Specimen



Figure 10: Credo Cube with shipping labels affixed

7.17. Package is now ready for shipment (Figure 11).



Figure 11 – Packaged Credo Cube ready for shipment

7.18. Hand off the package to the courier for shipment to TCPC. Contact TCPC immediately if pick up time needs to be rescheduled due to delays.

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**CLINICAL DOCUMENT**

Document number: TCPC-MNCHandbook  
Revision: 08  
Effective date: 01/12/2023  
Page 12 of 13

**8. REVISION HISTORY**

<b>Revision</b>	<b>Effective Date</b>	<b>Summary of Changes</b>
00	11/25/2016	Initial version of document.
01	12/23/2016	Added table with MNC collection quantities, information about anticoagulant and blood priming. Added picture and description about adding bubble wrap into the shipper
02	11/30/2017	Removed references to CHLA to make into a general document for use at all clinical sites
03	10/29/2018	Removed references to PLAT-02 and made document non-protocol specific.
04	02/25/2019	Changed title from 'Protocol' to 'Handbook' and changed document number from 'TCPC-MNCProtocol' to 'TCPC-MNCHandbook'. Added statement to make training unnecessary for subsequent studies if procedures are equivalent. Added revision history section.
05	02/07/2020	Remove section related to MNC collection. Change title to MNC shipping and handling handbook
06	04/13/2020	Remove instructions on MNC bag sampling. Step 5.4 and 5.5 conflict with instructions in the ICC owned MNC collection handbook.
07	08/31/2021	Change document title to be specific to external clinical sites. Update process as needed for accuracy. Update SRCI to SCTx.
08	01/12/2023	Remove definition for CBC. Remove instructions for CBC and white blood cell count.

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Page 13 of 13

**9. APPENDIX**

*Quick Bill of Lading Example:*

**Quick Bill of Lading**

Shipper Reference: TEST

Shipper: SEATTLE CHILDREN'S RESEARCH INSTITUTE  
ALEXANDRA SCHROEDER  
1120 OLIVE WAY  
SEATTLE WASHINGTON 98101  
UNITED STATES  
206-864-4041

Delivery Info: CHILDRENS HOSPITAL OF LOS ANGELES  
1600 SUNSET BLVD  
LOS ANGELES CALIFORNIA 90027  
UNITED STATES

Description/Commodity: APHERESIS

Special Instructions: Pick-Up PLEASE SUPPLY CREDO C4-2896 BIO-B46  
ABSORBENT MATERIAL AND TEMP IALE IV  
Delivery PLEASE SUPPLY CREDO C4-2896 BIO-B46  
ABSORBENT MATERIAL AND TEMP IALE IV

Shipper's Signature: \_\_\_\_\_  
Date and Time: \_\_\_\_\_

*TCPC Shipping Labels Examples:*

**Seattle Children's Research Institute  
Therapeutic Cell Production Core**

1920 Terry Ave  
Seattle, WA 98101

**DO NOT  
X-RAY**

**EXEMPT  
HUMAN  
SPECIMEN**