



## STEM CELL LABORATORY (STCL)



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Cellular Product Chain of Custody Form for Products Collected Outside NP FRM3

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**STCL-GEN-009 FRM3****Cellular Product Chain of Custody Form for Products Collected Outside NP**

Cooler # \_\_\_\_\_

ISBT 128 Barcode #: \_\_\_\_\_

*NOTE: For cellular products **collected outside the North Pavilion (NP)**, transported on public roads, and delivered to the **STCL**; the temperature upon packing and receipt must be recorded*

*Additional patient-related information about the collection of this product may also be included in the Electronic Medical Record*

1. Patient Name: \_\_\_\_\_  
 Patient History #: \_\_\_\_\_ DOB: \_\_\_\_\_  
*(Affix Patient Demographic Label)*

2. Donor Name: \_\_\_\_\_  
 Donor History #: \_\_\_\_\_ DOB: \_\_\_\_\_  
*(Affix Patient Demographic Label, if applicable)*

3. Collection Date: \_\_\_\_\_ Time Container Packed: \_\_\_\_\_ EST

4. Product integrity evaluated, labels ✓, paperwork ✓ and all deemed acceptable at the time of packing: *(No leaks, transcription or labeling errors, etc)*

\_\_\_\_\_  
*Name of person who packed cooler and qualified product*

5. Temp of container at time of packing 20°C -24°C\*? *(Check ONE)* ☐ Yes ☐ No

6. Serial # \_\_\_\_\_ *(Select ONE)* ☐ Thermometer ☐ Data Logger

7. Employee **delivering** product to the Stem Cell Laboratory (STCL) :

\_\_\_\_\_  
*Signature of person who delivered container* Date: \_\_\_\_\_ Time: \_\_\_\_\_ EST

8. Stem Cell Laboratory employee or designee **accepting** cellular product:

\_\_\_\_\_  
*Signature of person accepting product in STCL* Date: \_\_\_\_\_ Time: \_\_\_\_\_ EST

9. Temp of container upon receipt in STCL 20°C -24°C\*? *(Check ONE)* ☐ Yes ☐ No

*\* If the temperature upon receipt is out of range (20°C - 24°C), please notify the Medical Director / Attending Physician immediately and provide documentation regarding the disposition of the product (via e-mail)*

\_\_\_\_\_  
*Name of the MD notified of temperature excursion* Date: \_\_\_\_\_ Time: \_\_\_\_\_ EST

**\*If temperature is out of range, a Non-Conforming Product (NCP) form and/or Deviation**

**NCP # assigned:** \_\_\_\_\_ **or DEVIATION # assigned:** \_\_\_\_\_

**NOTE:** Instructions to download temp readings from data logger (Refer to *STCL-COLL-007 (JA9)*).

## Instructions for Completing the Cellular Product Chain-of-Custody Form

<b>In the field...</b>	<b>Record...</b>
Cooler #	Record the cooler number used to transport product.
ISBT 128 barcode	Place ISBT unique barcode here.
Form to be used for products collected outside the NP ( <i>ie. HPC, Apheresis, HPC, Marrow, etc</i> )	Products collected outside the North Pavilion and transported on public roads to the Stem Cell Laboratory.
1. Patient Name <i>Affix Label</i>	Name of Patient donating cells.
Patient History # <i>Affix Label</i>	Enter Patient's Duke History.
2. Donor Name ( <i>if applicable</i> ) <i>Affix Label</i>	Name of Donor who donated cellular product ( <i>if applicable</i> )
Donor's History # ( <i>if applicable</i> ) <i>Affix Label</i>	Donor's History # ( <i>if applicable</i> )
3. Collection Date	Record the date the product was collected
Time Container Packed	Time Container was packed for transport to the lab.
4. Product integrity evaluated, labels ✓, paperwork ✓ and deemed acceptable	Inspect the cellular product BEFORE it is placed inside the cooler to make sure bag is not compromised, mislabeled, etc
5. Temperature of container at time of packing	Check temperature inside the cooler BEFORE placing the cellular product inside the cooler for transport; <i>if unacceptable another cooler may need to be requested.</i>
6. Serial # (Thermometer or Data logger)	Record the serial # of the temperature probe and check whether it is a thermometer or data logger
7. Signature of person who packed and delivered cellular product to the Stem Cell Laboratory (STCL)	Signature of the person who packed and delivered the cellular product to the lab ( <i>ie. Nursing staff, MD, designated courier, etc</i> ), date and time
8. Signature of Stem Cell Laboratory employee accepting cellular product	Signature of laboratory personnel, or designee, accepting the cellular product in the laboratory, date, and time.
9. Temperature of transport container at the time of receipt in the STCL between 20°C - 24°C? Yes or No?	Once the temperature reading(s) from the thermometer or data logger have been reviewed/downloaded, ensure the temperature reading(s) is/are within 20°C -24°C. Respond YES or NO.
If the acceptable transport temperature range of <b>20 °C – 24 °C</b> has been exceeded, a Non-Conforming Product (NCP) form will need to be initiated and/or Deviation will need to be initiated in MasterControl. Record the NCP# _____ or DEV-XXXX that has been assigned ( <i>if applicable</i> ).	<p>IF the acceptable transport temperature range of 20 - 24°C has been exceeded, a Non-Conforming Product form will need to be initiated and/or a deviation will need to be initiated in MasterControl</p> <p>If NCP form and/or deviation was initiated, record the # of this chain of custody form.</p>
Instructions for downloading data from a data logger.	If a data logger was used in the transport container, refer to STCL-COLL-007 (JA9) for instructions of how to download the data, etc.

**Signature Manifest****Document Number:** STCL-GEN-009 FRM3**Revision:** 04**Title:** Cellular Product Chain of Custody Form for Products Collected Outside NP FRM3**Effective Date:** 07 Dec 2020

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**Document Release**

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