



STEM CELL LABORATORY (STCL)



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Cellular Product-Sample Chain of Custody FRM2

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Author: WATE02

Owner: WATE02

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STCL-GEN-009 FRM2
Cellular Product/Sample Chain of Custody Form

Cooler # _____ ISBT 128 Barcode # (if applicable): _____

*NOTE: For cellular products **distributed by the STCL and transported on public roads**; the temperature upon receipt must be recorded at the bottom of the form*

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: _____

4. Cellular Product **issued by** the Stem Cell Laboratory (STCL)

Signature of STCL Employee issuing product Date: _____ Time: _____ EST

5. Cellular Product **issued to** :

Signature of person transporting product Date: _____ Time: _____ EST

Serial # _____ (Select ONE) ☐ Thermometer ☐ Data Logger

Temperature of the container upon receipt is between 20°C - 24°C*? (Check ONE) ☐ Yes ☐ No

Person checking temperature upon receipt Date: _____ Time: _____ EST
 PRINT and SIGN

** 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 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: _____**

Return Completed Form to the Stem Cell Laboratory

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Cellular Product/Sample Chain of Custody Form

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

In the field...	Record...
Cooler #	Enter cooler number using to transport product
ISBT 128 barcode (if applicable)	Place ISBT unique barcode (if applicable)
Cellular products that are distributed by the STCL and transported on public roads , the temperature upon receipt is required; must complete Section at the bottom of the form	If products are transported on public roads, the temperature must be recorded upon receipt (at the bottom of the form)
1. Recipient # Name	Name of the Recipient whose product or sample is being distributed.
Recipient History #	Enter Recipient's Duke History
2. Donor Name (if applicable)	Name of Donor whose cellular product or sample is being distributed (if applicable)
Donor's History # (if applicable)	Donor's History # (if applicable)
3. Collection Date	Date cellular product or sample was collected
4. Cellular product issued by	Enter the signature of the STCL employee issuing the CP or sample, Date, and Time (EST).
5. Cellular product issued to	Enter signature of the person accepting the CP, Date, and Time (EST)
Serial # of Thermometer or Data Logger	Record the serial # of the thermometer or data logger used for this shipment. Select whether thermometer or data logger was used.
11. Time CP / sample accepted from STCL employee	Time designated courier accepted the CP / sample from the STCL employee (ET).
Serial # of thermometer or data logger used	Record the serial # of the temperature monitoring device used in the transport container. If not used, select N/A
Signature of person recording the temperature of container upon receipt	Record signature of person reading the temperature, date, and time (EST).
If temperature upon receipt is out of range	Contact medical director or attending physician to get instructions regarding disposition of the product, date, time (EST). <i>Provide documentation regarding the disposition of the product (via e-mail)</i>
If temperature upon receipt exceeds the range of 20-24°C, a NCP and/or DEV must be initiated to investigate the issue.	Record the NCP# and/or DEV# assigned or enter N/A in these fields, <i>if applicable</i> .

Signature Manifest**Document Number:** STCL-GEN-009 FRM2**Revision:** 04**Title:** Cellular Product-Sample Chain of Custody FRM2

All dates and times are in Eastern Time.

STCL-GEN-009 FRM2 Cellular Product-Sample Chain of Custody**Author**

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