

STEM CELL LABORATORY (STCL)



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STCL-GEN-009 FRM3

Cellular Product Chain of Custody Form for Products Collected Outside NP

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 mo also be included in the Electronic Medical Record 1. Patient Name: Patient History #:	Patient Name: Patient History #:		ISBT 128 Barcode #:	
1. Patient Name: Patient History #:	1. Patient Name: Patient History #:	roads, and delivered to the	<u>e STCL</u> ; the <u>temperature upon packing and receipt</u> mu	st be recorded
Patient History #:	Patient History #:	Additional patient-related inform	nation about the collection of this product may also be included in the Electronic	<mark>c Medical Record</mark>
2. Donor Name: Donor History #: DOB:	2. Donor Name: Donor History #:	-	DOB:	
Donor History #:	Donor History #:	ration History "		
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): Date:	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	2. Donor Name:		
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6. Serial #	5. Serial #		Name of person who packed cooler and qualified product	
7. Employee delivering product to the Stem Cell Laboratory (STCL):	7. Employee delivering product to the Stem Cell Laboratory (STCL): Date: Time: EST Signature of person who delivered container 8. Stem Cell Laboratory employee or designee accepting cellular product: Date: Time: EST Signature of person accepting product in STCL Date: Time: EST Fignature of person accepting product in STCL Temp of container upon receipt in STCL 20°C -24°C*?(Check ONE) \(\text{Y es} \) \(\text{No} \) *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) Date: Time: EST Name of the MD notified of temperature excursion	5. Temp of container a	at time of packing 20°C -24°C*? (Check ONE)	Yes□ No
7. Employee delivering product to the Stem Cell Laboratory (STCL):	7. Employee delivering product to the Stem Cell Laboratory (STCL): Date: Time: EST Signature of person who delivered container 8. Stem Cell Laboratory employee or designee accepting cellular product: Date: Time: EST Signature of person accepting product in STCL Date: Time: EST Signature of person accepting product in STCL P. Temp of container upon receipt in STCL 20°C -24°C*?(Check ONE) \(\text{Y es} \) \(\text{No} \) *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) Date: Time: EST Name of the MD notified of temperature excursion	6. Serial #	(Select ONE) Thermometer	Data Logger
Date: EST Signature of person who delivered container 8. Stem Cell Laboratory employee or designee accepting cellular product: Date: Time: EST Signature of person accepting product in STCL 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) Date: Time: EST Name of the MD notified of temperature excursion *If temperature is out of range, a Non-Conforming Product (NCP) form and/or Deviation or DEVIATION # assigned: or DEVIATION # assigned:	Date: Time: EST Signature of person who delivered container Stem Cell Laboratory employee or designee accepting cellular product: Date: Time: EST Signature of person accepting product in STCL Temp of container upon receipt in STCL 20°C -24°C*?(Check ONE) \(\text{Y es} \) \(\text{No} \) * If the temperature \(\text{upon receipt} \) is out of range \((20^{\circ}C - 24^{\circ}C) \), please notify the Medical Director / Attending Physician immediately and provide documentation regarding the disposition of the product (via e-mail) Date: Time: EST Name of the MD notified of temperature excursion			
Signature of person who delivered container 8. Stem Cell Laboratory employee or designee accepting cellular product: Date: Time: EST Signature of person accepting product in STCL 9. Temp of container upon receipt in STCL 20°C -24°C*?(Check ONE) \(\text{Yes} \) \(\text{No} \) * 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) Date: Time: EST Name of the MD notified of temperature excursion *If temperature is out of range, a Non-Conforming Product (NCP) form and/or Deviation or DEVIATION # assigned:	Signature of person who delivered container Stem Cell Laboratory employee or designee accepting cellular product: Date: Time: EST Signature of person accepting product in STCL Temp of container upon receipt in STCL 20°C -24°C*?(Check ONE) \(\text{Y es} \) \(\text{No} \) * 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) Pate: Time: EST Name of the MD notified of temperature excursion *If temperature is out of range, a Non-Conforming Product (NCP) form and/or Deviation	7. Employee <u>deliverin</u>	<u>ng</u> product to the Stem Cell Laboratory (STCL)	:
8. Stem Cell Laboratory employee or designee accepting cellular product: Date: Time: EST Signature of person accepting product in STCL 9. Temp of container upon receipt in STCL 20°C -24°C*?(Check ONE) \[\] Yes \[\] No * If the temperature \(\text{upon receipt}\) 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) Date: Time: EST Name of the MD notified of temperature excursion *If temperature is \(\text{out of range}\), a Non-Conforming Product (NCP) form and/or Deviation Or DEVIATION # assigned:	8. Stem Cell Laboratory employee or designee accepting cellular product: Date:		Date: Time: _	EST
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Signature of person accepting product in STCL 9. Temp of container upon receipt in STCL 20°C -24°C*?(Check ONE) \(\text{Y} \) \(\text{Y} \) \(\text{Ess} \) \(\text{No} \) * 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) \text{Date: Time: EST Name of the MD notified of temperature excursion} *If temperature is \(\text{out of range} \), a Non-Conforming Product (NCP) form and/or Deviation \(\text{NCP} \) # assigned: \(\text{or DEVIATION # assigned: } \)	Signature of person accepting product in STCL 20°C -24°C*?(Check ONE) * 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) Date: Time: EST Name of the MD notified of temperature excursion *If temperature is out of range, a Non-Conforming Product (NCP) form and/or Deviation		Date: Time:	EST
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Physician immediately and provide documentation regarding the disposition of the product (via e-mail)	Physician immediately and provide documentation regarding the disposition of the product (via e-mail) Date: Time: EST Name of the MD notified of temperature excursion *If temperature is out of range, a Non-Conforming Product (NCP) form and/or Deviation	\mathcal{J}		
Name of the MD notified of temperature excursion *If temperature is out of range, a Non-Conforming Product (NCP) form and/or Deviation NCP # assigned: or DEVIATION # assigned:	Name of the MD notified of temperature excursion *If temperature is out of range, a Non-Conforming Product (NCP) form and/or Deviation		upon receipt in STCL 20°C -24°C*?(Check ONE)	□Yes□ No
*If temperature is <u>out of range</u> , a Non-Conforming Product (NCP) form and/or Deviation NCP # assigned: or DEVIATION # assigned:	*If temperature is <u>out of range</u> , a Non-Conforming Product (NCP) form and/or Deviation	9. Temp of container u * If the temperature upon re	eceipt is out of range (20°C - 24°C), please notify the Medical Dir	ector / Attending
NCP # assigned: or DEVIATION # assigned:		9. Temp of container u * If the temperature upon re Physician immediately and p	eccipt is out of range (20°C - 24°C), please notify the Medical Dir provide documentation regarding the disposition of the product (Date: Time:	ector / Attending via e-mail)
		9. Temp of container u * If the temperature upon re Physician immediately and p	eccipt is out of range (20°C - 24°C), please notify the Medical Dir provide documentation regarding the disposition of the product (Date: Time:	ector / Attending via e-mail)
	NOTE : Instructions to download temp readings from data logger (Refer to STCL-COLL-007 (JA9).	9. Temp of container u * If the temperature upon re Physician immediately and p Name of the MD notified of *If temperature is out of re	eceipt is out of range (20°C - 24°C), please notify the Medical Dir provide documentation regarding the disposition of the product (Date: Time: ftemperature excursion ange, a Non-Conforming Product (NCP) form and/or	ector / Attending via e-mail) EST r Deviation

Stem Cell Laboratory, DUMC

Durham, NC

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<u>Instructions for Completing the Cellular Product Chain-of-Custody Form</u>

In the field	Record
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 (ie. HPC, Apheresis, HPC, Marrow, etc)	Products collected outside the North Pavilion and transported on public roads to the Stem Cell Laboratory.
1. Patient Name Affix Label	Name of Patient donating cells.
Patient History # Affix Label	Enter Patient's Duke History.
2. Donor Name (if applicable) Affix Label	Name of Donor who donated cellular product (if applicable)
Donor's History # (if applicable) Affix Label	Donor's History # (if applicable)
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 $\sqrt{\ }$, paperwork $\sqrt{\ }$ 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</i> unacceptable another cooler may need to be requested.
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 (ie. Nursing staff, MD, designated courier, etc), 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 20 °C – 24 °C 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#	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
or DEV-XXXX that has been assigned (<i>if</i> applicable).	If NCP form and/or deviation was initiated, record the # of this chain of custody form.
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.

STCL-GEN-009 FRM3 Cellular Product Chain of Custody Form for Products collected outside the NP Instructions

Stem Cell Laboratory, DUMC

Durham, NC

Signature Manifest

Document Number: STCL-GEN-009 FRM3 Revision: 04

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Effective Date: 07 Dec 2020

All dates and times are in Eastern Time.

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

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Document Release

Name/Signature	Title	Date	Meaning/Reason
Sandy Mulligan (MULLI026)		19 Nov 2020, 05:59:03 PM	Approved