STEM CELL LABORATORY (STCL)

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DOCUMENT TITLE:

Packaging and Transporting Non-Frozen Cellular Products Locally

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STCL-GEN-009
PACKAGING AND TRANSPORTING NON-FROZEN CELLULAR PRODUCTS LOCALLY

1 PURPOSE

1.1 The purpose of this procedure is to describe how designated staff will package, transport, and locally ship non-frozen cellular products to and from the collection site, processing lab, and/or transplant facility.

2 INTRODUCTION

2.1 This procedure includes the instructions for packaging, transporting, and locally shipping non-frozen cellular products to include stem cells, bone marrow, thawed cord blood, granulocytes, dendritic cells, lymphocytes, donor lymphocytes, etc. All cellular products will be stored and/or transported to the clinical facility for infusion or to the processing laboratory in a transport container (*cooler*) while maintaining a temperature between 20-24°C for up to four hours. All cellular products must be in the laboratory within four hours from the end time of collection.

2.2 Products transported locally **on public roads** are required to have the temperature checked and recorded at the time of receipt in the laboratory or the transplant facility.

3 SCOPE AND RESPONSIBILITIES

3.1 The Adult and Pediatric Medical Directors, Laboratory Manager, Collection and Processing Staff, and Quality Manager are responsible for ensuring that the requirements of this procedure are successfully met.

3.2 Stem Cell Laboratory staff, Apheresis staff, and any personnel, who receive cellular products in the laboratory or transplant facility, are responsible for ensuring that the requirements of this procedure are successfully met and that temperatures are recorded on the appropriate chain of custody forms.

4 DEFINITIONS/ACRONYMS

4.1	NCP	Non-Conforming Products
4.2	TSP	Temperature Stabilization Packs
4.3	NP	North Pavilion
4.4	STCL	Stem Cell Laboratory
4.5	OR	Operating Room

5 MATERIALS

5.1 Leak proof plastic bags, e.g., Ziploc

5.2 Absorbent material (*chux pad*)

5.3 Labels (*address, biohazard, "Do Not X-ray"*)

5.4 Temperature stabilization pack

5.5 Rigid shipping tube (*if applicable*)

6 EQUIPMENT

6.1 Playmate cooler *(or validated equivalent transport container)*

7 SAFETY

7.1 Wear all applicable personal protective equipment when handling potentially hazardous blood and body fluids to include, but not limited to, gloves, lab coats, goggles, etc.

8 PROCEDURE

8.1 Local Transport

8.1.1 Local transport includes all deliveries made within 4 hours or less; these units must be picked up and/or delivered by designated staff or approved commercial/local couriers.

8.1.2 Products **collected inside the North Pavilion** (NP) (*ie. ABMT Apheresis area, OR in the North Pavilion, etc*) that are **NOT transported on public roads** are NOT required to have the temperature recorded at the time of receipt in the laboratory. Use *STCL-GEN-009 FRM1 Cellular Product Chain of Custody Form* to capture information regarding patient/donor information, collection date, product type, signatures of staff delivering and receiving product in the laboratory.

8.1.3 Products **distributed by the STCL** (*to N5200, N9200, CHC, etc*) and **transported on public roads** are required to have the temperature checked upon receipt in the laboratory or transplant facility using *STCL-GEN-009 FRM2 Cellular Product / Sample Chain-of-Custody Form*. If the temperature exceeds 20 - 24°C at the time of receipt, notify the medical director and/or attending physician to get instructions regarding the final disposition of the product (*ie. infuse it and initiate a Non-Conforming Product (NCP) and/or deviation; return the product to the laboratory, etc*). Attach documentation of the notification and the instructions to the form and return to the STCL.

8.1.4 Products that are collected **outside the North Pavilion** (*ie. CHC Apheresis room, OR in Duke North, etc*) and **transported on public roads** are required to have the temperature checked upon receipt. *Use STCL-GEN-009 FRM3 Cellular Product Chain of Custody Form for Products Collected Outside NP* to capture patient/donor information, collection date, temperature of the container, etc. If the temperature exceeds 20 - 24°C at the time of receipt, notify the medical director and/or attending physician to get instructions regarding regarding the final disposition of the product (*ie.*

infuse it and initiate a Non-Conforming Product (NCP) and/or deviation; return the product to the laboratory, etc). Attach documentation of the notification and the instructions to the form and return to the STCL

8.2 Prepare the Transport Container

8.2.1 Select a validated Playmate cooler for transport container.

8.2.2 To the outside of the transport container, attach the following labels:

8.2.2.1 Medical Specimen

8.2.2.2 Do not X-ray

8.2.2.3 Receiving facility's name and address (i.e. processing lab)

8.2.2.4 Responsible person's name and phone number at receiving facility

8.2.3 Apply a biohazard label to the transport container, if test results are positive for any infectious disease markers listed in Donor Evaluation or if infectious disease testing results are pending.

8.3 Pack the Unit

8.3.1 Protect the unit from extreme changes in temperature.

8.3.2 Place the stabilization pack on the bottom of the transport container,

8.3.3 Place enough absorbent material to absorb the contents of the shipment (chux pad).

8.3.4 Place each unit inside a leak-proof plastic bag, e.g., Ziploc.

NOTE: *If transporting blood samples in tubes, place them in a rigid shipping tube, and then seal them in a separate leak-proof plastic bag.*

8.3.5 NIST-traceable thermometer or data logger should be placed inside the transport container so the temperature upon receipt, **if transported on public roads**, can be recorded as per regulatory requirements. Record whether the temperature at the time of receipt was within acceptable range of 20 - 24°C on the appropriate Chain of Custody Form

8.3.6 Include one of the following forms along with each cellular product in the cooler:

8.3.6.1 For every cellular product being transported from **within the North Pavilion (NP)** from the collection facility to the STCL laboratory for processing, complete and include a *STCL-GEN-009 FRM1 Cellular Product Chain of Custody Form* for each product contained in the cooler. This form should be completed when the product(s) arrives in the laboratory to reflect the date, time, and signature of the person transporting the cells to the laboratory along with the date, time, and signature of the person accepting the cells in the laboratory. The *STCL-GEN-009*

FRM1 Cellular Product Chain of Custody Form will be placed in the patient's laboratory file.

8.3.6.2 For every cellular product being transported **on public roads** from the STCL laboratory to a transplant facility **outside of the North Pavilion (NP)** or from a collection facility **outside the North Pavilion (NP)**, complete and include *STCL-FORM-056 Cellular Therapy Infusion Request Form* and *STCL-GEN-009 FRM2 Cellular Product / Sample Chain-of-Custody Form* or *STCL-GEN-009 FRM3 Cellular Product Chain of Custody Form for Products Collected Outside NP*. The chain of custody forms will reflect the date, time, and signature of the person transporting the cells from the laboratory to the transplant facility along with the date, time, and signature of the person accepting the cells at the transplant facility. The temperature upon receipt in the laboratory or the transplant facility, for those products collected **outside the North Pavilion (NP) and transported on public roads**, should be recorded on the bottom of the form. The original *STCL-SOP-056 Cellular Therapy Infusion Request Form* will remain with the product and a copy of this form (*including signatures*) will remain on file with the associated processing record in the laboratory. The original chain of custody form should be returned to the laboratory and placed in the patient's laboratory file.

8.4 Put the unit and any samples inside the transport container on top of the absorbent material (chux pad).

NOTE: No more than four cellular products can be transported in a cooler at one time.

8.4.1 Make sure the person transporting the cellular product(s) signs the appropriate form or forms accompanying each product in the transport container (cooler).

8.4.2 Place the signed form/s with the appropriate product in the transport container (cooler).

8.4.3 Close the transport container (cooler) securely.

8.4.4 Transport the product (*done by staff or designated courier*)

8.4.5 **Never leave the transport container, containing cellular products, unattended or with unauthorized personnel**.

8.5 Deliver the cellular products in the transport container to the processing laboratory and/or transplant facility as quickly as possible to ensure that the integrity of the cellular products is not compromised.

8.5.1 Upon delivery of the cellular products to the laboratory from **within the North Pavilion**, be sure the person transporting the products to the

laboratory has completed *STCL-GEN-009 FRM1 Cellular Product Chain-of-Custody Form.*

8.5.2 Upon delivery of the cellular products **transported on public roads** to the laboratory or transplant facility, be sure the person transporting the cellular products in the transport container has completed the *STCL-GEN-009 FRM2 Cellular Product/Sample Chain-of-Custody Form*, the *STCL-GEN-009 FRM3 Cellular Product Chain-of-Custody Form for Products Collected Outside NP*, and/or the *STCL-FORM-056 Cellular Therapy Infusion Request Form* to reflect the date, time, and signature of both the person who transported the product and the person who received *(accepted)* the product. The temperature of the container upon receipt should be reflected on the bottom of the chain of custody form.

8.5.2.1 Whomever accepts the cellular product in the laboratory or at the transplant facility, should record the temperature on the bottom of the chain of custody form.

8.5.2.2 If the temperature is outside the acceptable range reflected on the form, notify the medical director and/or transplant physician immediately so they can provide instructions regarding how to proceed.

8.5.2.3 Record the name of the person who was notified of the temperature excursion and what decision was made regarding the final disposition of the product.

8.5.2.4 Because expiration date and timelines are not flexible, NCP and/or deviations may have to be initiated/generated after the incident occurs.

9 RELATED DOCUMENTS/FORMS

9.1 STCL-GEN-009 FRM1 Cellular Product Chain-of-Custody Form

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

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

9.4 STCL-FORM-056 Cellular Therapy Infusion Request Form

10 REFERENCES

10.1 American Association of Blood Banks. Standards for Hematopoietic Progenitor Cell and Cellular Product, current edition.

10.2 American Association of Blood Banks. Standards for Blood Banks and Transfusion Services, current edition.

10.3 Foundation for the Accreditation of Hematopoietic Cell Therapy (FACT), Standards for Hematopoietic Progenitor Cell Collection, Processing and Transplantation, current edition.

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
08	B. Waters-Pick	• Added Section 2.2 • Updated Section 5 to remove document names • Added Sections 8.1.2 – 8.1.4 • Removed 8.2.3.5 • Added Section 8.3.5 • Modified Sections 8.3.6.1 and 8.3.6.2 • Modified Sections 8.5.1 and 8.5.2 to clarify which chain of custody forms should be used • Added Sections 8.5.2.1 thru 8.5.2.4 • Updated Section 9 to provide the document numbers

Signature Manifest

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Management

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