



## STEM CELL LABORATORY (STCL)



**DOCUMENT NUMBER:** STCL-DIST-001 JA1

**DOCUMENT TITLE:**

Incoming NMDP Products - STCL Checklist JA1

**DOCUMENT NOTES:**

### Document Information

**Revision:** 03

**Vault:** STCL-Distribution-rel

**Status:** Release

**Document Type:** Distribution

### Date Information

**Creation Date:** 17 Nov 2016

**Release Date:** 21 Dec 2016

**Effective Date:** 21 Dec 2016

**Expiration Date:**

### Control Information

**Author:** WATE02

**Owner:** WATE02

**Previous Number:** STCL-DIST-001 JA1 Rev 02 **Change Number:** STCL-CCR-363

**STCL-DIST-001 JA1  
Incoming NMDP Products – STCL Checklist**

ISBT 128 Barcode Assigned:

*N/A = Not Applicable*

Collection Date: \_\_\_\_\_

Recipient's Name: \_\_\_\_\_

Storage Date: \_\_\_\_\_

NMDP Donor #: \_\_\_\_\_

Distribution Date: \_\_\_\_\_

NMDP Recipient #: \_\_\_\_\_

**NOTE:** Complete this checklist as a tool when receiving / testing/ processing / distributing cellular products in the Stem Cell Laboratory that have been collected by other Collection Centers (CC) on behalf of the National Marrow Donor Program (NMDP).

**PRE-PRODUCT ARRIVAL IN THE STEM CELL LAB:**

1. Make sure the NMDP folder contains the following:

☐ Patient Demographic Information and ABO/Rh Printout  
☐ NMDP Prescription Form  
☐ NMDP Donor Information Report  
☐ NMDP Courier's Itinerary

Initials \_\_\_\_\_
  
2. ☐ Use these documents to **verify** the NMDP Donor and Recipient IDs, donor information, and recipient information thoroughly. Make sure processing requirements, if applicable (i.e. ABO incompatibility) are noted on donor labels and on the outside cover of red NMDP folder provided by Janet Adcock or designee.

Initials \_\_\_\_\_
  
3. ☐ Ensure that the infusion orders have been prepared and signed by the attending physician. **Please pay close attention to any additional processing instructions, such as the Physician's recommended dosage to cap for infusion that might be reflected on the infusion order, etc.**

Initials \_\_\_\_\_
  
4. ☐ Assign an ISBT barcode label to **each** product arriving to the lab. Place barcode on all appropriate paperwork and affix a barcode to the product bag.

Initials \_\_\_\_\_
  
5. ☐ Order HPC Harvest or Leukapheresis (depending on product type) in Beaker.

Initials \_\_\_\_\_

6. Assemble the required paperwork and complete all applicable information and affix the barcodes.

- ☐ STCL-GEN-009 (FRM1) Cellular Product/Sample Chain of Custody  
(Place on top of the NMDP folder to ensure it is signed by the courier upon arrival to the STCL)
- ☐ NMDP Checklist
- ☐ STCL-FORM-049 Processing Lot # - Incoming Cellular Products
- ☐ STCL-FORM-040 Peripheral Blood Progenitor Cell Worksheet
- ☐ STCL Billing Log
- ☐ STCL-PROC-022 FRM1 STCL HPCA Worksheet
- ☐ STCL-FORM-064 Manual Differential Worksheet – Clinical Products
- ☐ FLOW-GEN-012 FRM5 Flow Cytometry Worksheet
- ☐ M0226 form (attach labels from the product bag on this form)

Initials \_\_\_\_\_

7. ☐ The current recipient's weight can be found in EPIC, but call the clinic/floor and request a current weight to **CONFIRM** this information if EPIC is not accessible.

Initials \_\_\_\_\_

8. Assemble the following and label them appropriately.

- ☐ 3 - Tubes for ABO/Rh
- ☐ 2 - Tubes for cell count and viability
- ☐ 1 - sterile Nunc vial for HPCA (Beaker label) (0.5 mls)  
(**NOTE:** If Bone Marrow, 4 mL for HPCA Basic)
- ☐ 1 – non-sterile tube for (Beaker label) (0.5 mls)
- ☐ 2 - sterile Nunc vials for cryopreservation (3.0 mls (1 ml/vial))
- ☐ 1 cytoprep (*to be prepared from HCPA specimen in the HPCA Area*)
- ☐ one set of culture bottles (aerobic / anaerobic) (1.0 mls per bottle)

Initials \_\_\_\_\_

9. ☐ Be familiar with the courier's flight itinerary and the estimated arrival times. Be available in the laboratory to answer the courier's phone call after their flight lands at RDU (or elsewhere if there are delays). Most importantly, make sure they know to come to North Pavilion and **NOT** the main hospital (Duke North) since this does tend to confuse couriers coming to our facility.

Initials \_\_\_\_\_

**PRODUCT ARRIVAL IN THE STEM CELL LAB:**

1. ☐ The courier should call once he/she has arrived to North Pavilion so the STCL employee can meet and escort him/her to the laboratory. Initials \_\_\_\_\_
2. ☐ Have the courier sign the *Cellular Product/Sample Chain of Custody*. Initials \_\_\_\_\_
3. ☐ Complete the NMDP forms provided by the courier. Accept the paperwork and initial as received where indicated. Keep all the forms and place them in the recipient's laboratory folder.



**(NOTE: Record Duke as TC Code 546 on NMDP documentation).**

Initials \_\_\_\_\_

4. ☐ Be sure to inspect the product upon arrival to:
  - Verify that the product is properly labeled.
  - Verify that all necessary paperwork accompanied the product.
  - Ensure there are no visible problems such as leaks, tears, clumps, or flaws in the bag housing the cellular product.
  - Ensure there is no visual evidence of microbial contamination.
  - If there are any discrepancies or problems noted, notify the laboratory manager or designee immediately so that corrective action can be taken. If deemed appropriate, the laboratory manager or designee will initiate a *Deviation, Non-Conforming Product* form, etc.

Initials \_\_\_\_\_
5. ☐ With the courier, check the labeling of the product(s) and the blood tube(s). Initial the correct form as verification that the labeling is correct. Place the blood tube(s) in the designated, monitored refrigerator.
 

Initials \_\_\_\_\_
6. ☐ If the courier is an international traveler, print and sign your name on the line for the Attending Physician. Usually the courier will need this form and some other paperwork faxed to the fax number indicated on the bottom of the form. When faxing this information, remember to enter 1 before the area code or 011 if the fax is going outside the USA.
 

Initials \_\_\_\_\_
7. ☐ If the product is to be processed the next day, place it in the designated, monitored refrigerator for overnight storage. **Bone marrow** being held overnight should be placed undisturbed in a biological safety cabinet (BSC) at room temperature unless otherwise specified. **Do NOT turn on the UV light in that BSC!!**

Initials \_\_\_\_\_
8. ☐ As a courtesy to the courier, please make sure he/she knows which hotel they are staying for the night (*if applicable*) and how to get to their hotel. Occasionally, it is necessary to call a taxi for them (given some late hour deliveries). Do not hesitate to ask the security officers if they can assist in contacting a taxi for the couriers.
 

Initials \_\_\_\_\_
9. ☐ Please notify the next shift of any pertinent information regarding the product, such as processing, storage location or changes in infusion orders, etc.
 

Initials \_\_\_\_\_

**PROCESSING IN THE STEM CELL LAB:**

1. ☐ Process the product, as indicated, using internal standard operating procedures.
 

Initials \_\_\_\_\_

2. ☐ For all NMDP products, tare the collection bag (or use 43.3 correction factor) and then **divide by a factor of 1.06** to obtain the final product volume. This factor accounts for the weight of the bag and the estimated product volume which is needed for processing. (**NOTE:** As a general rule, check the weight recorded for the product by the collection site to make sure the volumes are close to one another).

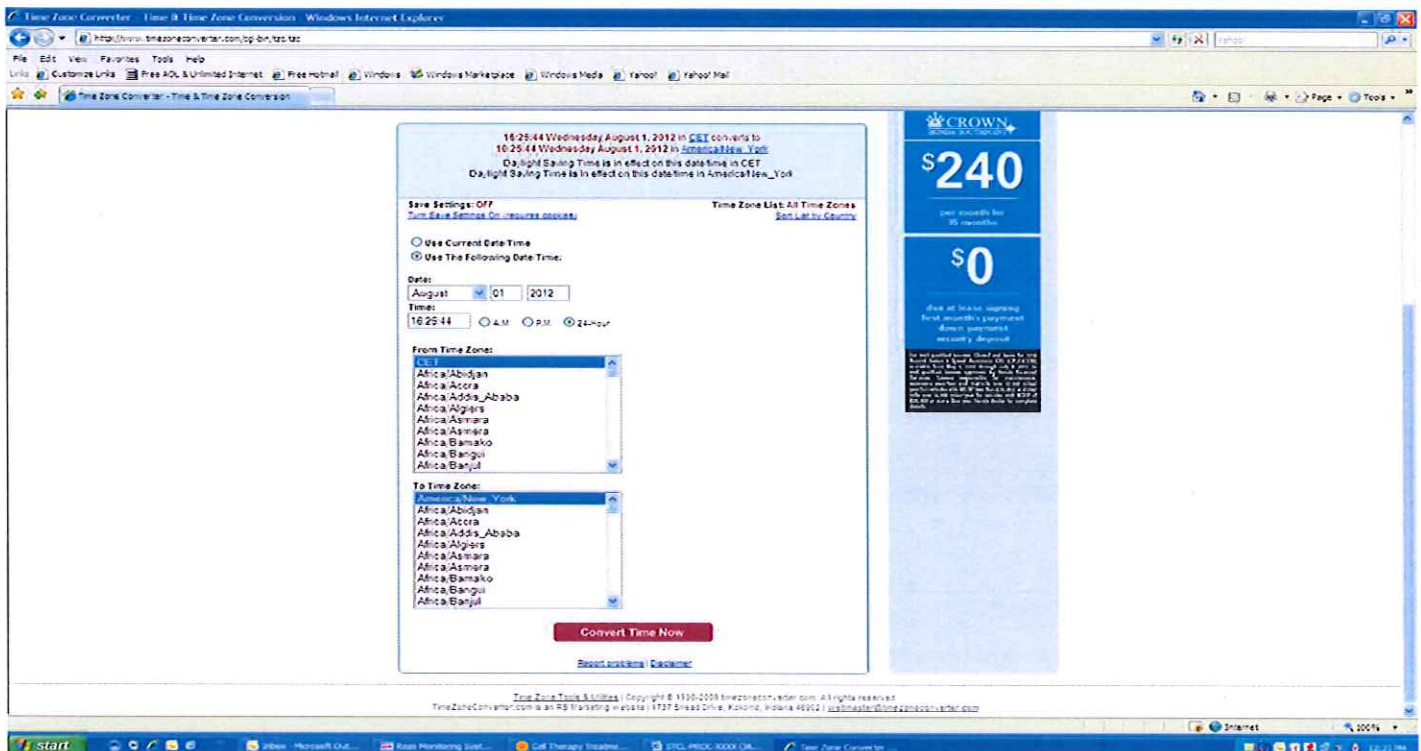
Initials \_\_\_\_\_

3. ☐ Perform a cell count, trypan blue viability, ABO/Rh confirmation, and cultures (to check sterility). Prepare slides for differentials (*if Bone Marrow*) and send designated samples for flow cytometry and HPCA testing. Prepare two (2) nunc vials for cryopreservation. Refer to internal standard operating procedures (i.e. viability, ABO/Rh testing, etc.)

Initials \_\_\_\_\_

4. ☐ For international collections, make sure the collection time is converted to Eastern Standard Time and noted on PBPC worksheet. Refer to the following website: <http://www.timezoneconverter.com/cgi-bin/tzc.tzc>. Chose "Use the following Date/time; enter the date/time of collection; chose CET (from time zone) to America-New York (to time zone); select "Convert Time Now". Notice at the top of the screen UNDER the adjusted times, that daylight savings time IS IN EFFECT (that is the reason America-New York is chosen instead of EST).

Initials \_\_\_\_\_



5. ☐ Next day processing should, at minimum, include a repeat cell count, trypan blue viability, and flow cytometry testing.

Initials \_\_\_\_\_

6. ☐ RBC depletions are occasionally done on 2<sup>nd</sup> shift (depending on the amount of incompatible rbc's in the product). Contact the attending physician to determine if RBC depletion is required or not. Plasma depletions are performed on the infusion day (**NOT** the day before) because cellular products are more stable when suspended in plasma.

Initials \_\_\_\_\_

7. ☐ Finish preparing the product for infusion according to internal standard operating procedures.

Initials \_\_\_\_\_

8. ☐ Before distributing the product,

- Verify that the product is properly labeled.
- Verify that all necessary paperwork accompanies the product including:
  - *Summary of Donor Eligibility*
  - *STCL-FORM-056 Cellular Therapy Infusion Request Form*
  - *STCL-SOP-050 Infusion Form*
  - *Circular of Information (COI) – not usually distributed with the products because COI have been made available at each infusion location*
- Inspect the product to ensure there are no visible problems such as leaks, tears, clumps, or flaws in the bag housing the cellular product.
- Inspect the product to ensure there is no evidence of microbial contamination.
- If there are any discrepancies or problems noted, notify the laboratory manager or designee immediately so that corrective action can be taken. If deemed appropriate, the laboratory manager or designee will initiate an *Event Report, Non-Conforming Products* form, etc.
- Timely resolution of any problems is imperative since a patient is awaiting this cellular product for transplantation.

Initials \_\_\_\_\_

9. ☐ Always contact the ABMT Clinic, N5200, N5100, N9200, etc. at least 30 - 60 minutes before the infusion so the nursing staff has time to pre-medicate the recipient ahead of time.

Initials \_\_\_\_\_

10. ☐ Attach a saline bag to the product bag (*used to rinse the bag*) and make sure there is at least one unused port available for the nurses to spike into.

Initials \_\_\_\_\_

11. ☐ Complete CIBMTR form and place in the red folder designated for Janet or designee. Include copies of WBC printout, differential form, and flow results.

Initials \_\_\_\_\_



**Signature Manifest****Document Number:** STCL-DIST-001 JA1**Revision:** 03**Title:** Incoming NMDP Products - STCL Checklist JA1

All dates and times are in Eastern Time.

**STCL-DIST-001 JA1 Incoming NMDP Products - STCL Checklist JA1****Author**

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		21 Nov 2016, 04:42:22 PM	Approved

**Manager**

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		21 Nov 2016, 04:42:33 PM	Approved

**Medical Director**

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		21 Nov 2016, 05:12:59 PM	Approved

**Quality**

Name/Signature	Title	Date	Meaning/Reason
John Carpenter (JPC27)		22 Nov 2016, 10:22:02 AM	Approved

**Document Release**

Name/Signature	Title	Date	Meaning/Reason
Sandy Mulligan (MULLI026)		07 Dec 2016, 05:48:56 PM	Approved