**DOCUMENT NUMBER:** STCL-COLL-007 JA11

**DOCUMENT TITLE:**
Blue Box Insulated Shipper Inspection and Cleaning

**DOCUMENT NOTES:**

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Document Information

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Date Information

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STCL-COLL-007 JA11
Blue Box Insulated Shipper Inspection and Cleaning

1 PURPOSE
1.1 The purpose of this procedure is to describe the process for inspection and cleaning of the insulated shipping container used in the Stem Cell Laboratory at Duke University Medical Center.

2 INTRODUCTION
2.1 Insulated blue box shipping containers are used to transport supplies to and from donors at non-fixed collection sites to the Stem Cell Laboratory at Duke University Medical Center.

2.2 The blue box and its components should be stored at an acceptable temperature range. Each shipper is validated to maintain a temperature range between 4°C-30°C for 36 hours. The optimal temperature of the cord blood unit during transit should be between 14°C-28°C.

2.3 An electronic data logger is included to record the temperature during transit to the STCL.

2.4 All components of the blue box insulated shipper must be in good working condition and inspected on a regular basis.

3 SCOPE AND RESPONSIBILITIES
3.1 The STCL Medical Director, Lab Manager, and designated STCL staff are responsible for ensuring the requirements of this procedure are successfully met.

4 DEFINITIONS/ACRONYMS
4.1 STCL Stem Cell Laboratory
4.2 QC Quality Control
4.3 °C degrees Celsius
4.4 UN3373 United Nations Biological Hazard Number for shipping biological specimens

5 MATERIALS
5.1 Germicidal wipes (e.g. Clorox Germicidal Wipes)
5.2 Insulated shipping container
   5.2.1 (1) Silver foil Styrofoam lid
   5.2.2 (1) Flexible grey urethane plug
   5.2.3 (2) Exogel panels (white temperature stabilizing panels)
   5.2.4 (1) Cryopak pouch (clear gel filled pouch) in ziplock bag
6 EQUIPMENT

6.1 Insulated shipping container, numbered and validated
   6.1.1 Outer corrugated container (blue shell)
   6.1.2 Silver Styrofoam liner and lid

7 SAFETY

7.1 Wear all appropriate personnel protective equipment when handling potentially infectious blood and body fluids, to include, but not limited to, gloves, lab coat, etc.

8 PROCEDURE

8.1 Placing NEW Blue Box Shipping containers into service
   8.1.1 Insulated shippers will come pre-assembled from manufacturer with the following components:
      8.1.1.1 Insulated shipping container
      8.1.1.1.1 (1) Silver foil Styrofoam lid
      8.1.1.1.2 (1) Flexible grey urethane plug
      8.1.1.1.3 (2) Exogel panels (white temperature stabilizing panels)
      8.1.1.1.4 (1) Cryopak pouch (clear gel filled pouch) in ziplock bag
   8.1.2 Each new shipper will be labeled with the following:
      8.1.2.1 UN3373 Label
      8.1.2.2 STCL Label including address and contact information
      8.1.2.3 Do NOT X-Ray
      8.1.2.4 Private Cord Blood Bank Label
      8.1.2.5 Box # assigned
   8.1.3 New, properly labeled insulated shippers are numbered in sequential order and documented on a STCL-COLL-007 FRM7 Blue Box Insulated Shipper Inspection and Cleaning Log.

8.2 Inspection and Cleaning
   8.2.1 Visual inspection of shippers will take place after each shipper has been received and unpacked.
   8.2.2 Visual inspection will include checking for damage or excessive soiling of any of the following that would interfere with proper use of the shipping container.
      8.2.2.1 Outer corrugated container
      8.2.2.2 Silver Styrofoam liner and lid
8.2.2.3 Exogel panel(s)
8.2.2.4 Flexible grey urethane plug
8.2.2.5 Cryopak pouch
8.2.2.6 Ziplock bag
8.2.2.7 If damage or excessive soiling is noted on any items, proceed to section 8.2.3 and record on STCL-COLL-007 FRM7 Blue Box Insulated Shipper Inspection and Cleaning Log.

8.2.3 Cleaning of shipping containers will take place after each shipping container has been received and unpacked.
8.2.3.1 Remove Silver Styrofoam lid, flexible grey urethane plug, Exogel panels, and Cryopak pouch in ziplock bag from shipping container.
8.2.3.2 Discard any soiled absorbent pads.
8.2.3.3 Wipe down the inside of the Silver Styrofoam liner and outside of the outer corrugated container with germicidal wipes and set aside to dry.
8.2.3.4 Wipe down the exterior and interior of the flexible grey urethane plug, Exogel panels, Cryopak pouch, and ziplock bag with germicidal wipes and allow to air dry.
8.2.3.5 Once shipping container is completely dry, it can be repacked for use.
8.2.3.6 Record inspection and cleaning results as appropriate on STCL-COLL-007 FRM7 Blue Box Insulated Shipper Inspection and Cleaning Log.

8.2.4 Removing shipping container from service
8.2.4.1 Any shipping container that is damaged beyond repair must be removed from service and discarded. Complete STCL-COLL-007 FRM7 Blue Box Insulated Shipper Inspection and Cleaning Log to reflect the date the shipping container was taken out of service.

9 RELATED DOCUMENTS_FORMS
9.1 STCL-COLL-007 Autologous and Directed CBU Donations
9.2 STCL-COLL-007 FRM7 Blue Box Insulated Shipper Inspection and Cleaning Log

10 REFERENCES
10.2 Foundation for the Accreditation of Hematopoietic Cell Therapy (FACT) and
Netcord-FACT International Standards for Cord Blood Collection, Processing,

10.3 21 Code of Federal Regulations part 1270, Human Tissue Intended for
Transplant.

10.4 21 Code of Federal Regulations part 1271, Human Cells, Tissue and Cellular and
Tissue-based Products.

10.5 21 Code of Federal Regulations part 211, Current Good Manufacturing Practice
for Finished Pharmaceuticals.

11 REVISION HISTORY

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### Signature Manifest

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**Title:** Blue Box Insulated Shipper Inspection and Cleaning

All dates and times are in Eastern Time.

### STCL-COLL-007 JA11 Blue Box Insulated Shipper Inspection and Cleaning

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