# PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

**DOCUMENT NUMBER:** PBMT-GEN-060  
**DOCUMENT TITLE:** Infusion of Thawed Autologous and Allogeneic Cord Blood Cells for Patients with Brain Injuries  
**DOCUMENT NOTES:** Dr. J. Sun, Dr. J. Kurtzberg.

## Document Information

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PBMT-GEN-060
INFUSION OF THAWED AUTOLOGOUS AND ALLOGENEIC CORD BLOOD CELLS
FOR PATIENTS WITH BRAIN INJURIES

1 PURPOSE
1.1 To outline the procedure for the infusion of thawed autologous or allogeneic cord blood cells in patients with brain injuries. These cryopreserved products have been shipped to the Duke Stem Cell Transplant Laboratory (STCL) and thawed and washed for removal of DMSO and volume reduction. After processing and configuration for reinfusion, the product is transported to the patient’s bedside for infusion.

2 INTRODUCTION
2.1 On the day of infusion or transplantation, cryopreserved autologous or allogeneic umbilical cord blood cells are prepared for infusion in the STCL.

2.1.1 The clinical team confirms that the infusion will occur and provides the weight of the patient to the STCL within a few days of the scheduled infusion.

2.2 Umbilical cord blood cells may be prepared for administration in a syringe or a bag. If prepared in a bag, an infusion set is provided for use at the patient’s bedside. This set is comprised of the bag of cells to be infused which has been sterile docked to a bag of normal saline. The saline will be used to rinse the transplant bag and tubing after the cells are infused.

2.3 If provided in a syringe, the syringe is attached to stopcock to allow and primed tubing.

2.4 The patient is pre-medicated with Benadryl, steroids, +/- Tylenol 5-60 minutes prior to administration of the cells to prevent infusion-related reactions.

3 SCOPE AND RESPONSIBILITIES
3.1 The Laboratory Manager, BMT Medical Director of the Pediatric inpatient unit (5200), and the Pediatric BMT Clinic and Day Hospital, Children’s Health Center (CHC), Nurse Manager, attending physician on service and/or the clinical study team are responsible for ensuring the requirements of this procedure are successfully met.

4 DEFINITIONS/ACRONYMS
4.1 DMSO – Dimethyl sulfoxide
4.2 STCL – Stem Cell Transplant Lab
4.3 VDH – Valvano Day Hospital
5 MATERIALS

5.1 Transplant bag from STCL
5.2 Normal Saline Attachment in Satellite Bag
5.3 Y-Type Blood/Solution Set with Standard Blood Filter (170-260 micron filter)
5.4 BD 10 Luer-Lock Syringe
5.5 3-way stopcock
5.6 Three (5ml) Normal Saline Syringes
5.7 Tape
5.8 Mask
5.9 Tourniquet
5.10 Sterile Gloves
5.11 Alcohol Preps (10)
5.12 2X2 gauze (4)
5.13 4X4 gauze (2)
5.14 Tegaderm
5.15 Two each 24 gauge angiocath needles 5/8 and ¾
5.16 IV Fluids – D5 ¼ NS
5.17 STCL-SOP-050 Infusion Form
5.18 Accompanying paperwork

Specimen Requirements:
Thawed, appropriately labeled, transplant product either (A) in a bag docked to
second bag of normal saline or (B) in a syringe with a stopcock and primed
tubing.

6 EQUIPMENT

6.1 IV Syringe Pump
7 SAFETY

7.1 Appropriate PPE must be worn when handling cellular therapy products.

8 PROCEDURE

8.1 Patient will arrive to McGovern-Davison Children's Health Center for check-in at the front desk. Patient will be weighed, measured, and vital signs taken. Patient armband will be placed by clinic staff. RN will verify armband by asking parent the child’s name and date of birth just prior to administration of any medications.

8.2 The Nurse Practitioner will write premedication orders and post IV hydration orders and enter into EPIC.

8.3 The product will be accepted by either a VDH RN or one of the PBMT Nurse Clinicians working with the brain injury population.

8.4 Two Nurse Clinicians, Nurse Practitioners, or Physicians will verify the product to be infused by double-checking the paperwork to the product.

8.5 Two Nurse Clinicians, Nurse Practitioners, or Physicians will then verify the product to the patient’s armband and confirm that the patient has received the premedications prior to initiating the infusion.

8.6 Apply probe to patient to monitor heart rate and O2 saturations during the infusions.

8.7 If the product is in a bag, the physician will then prepare the product using the Y-Site Blood tubing, first roller clamp one of the two double spikes and roller clamp the primary line of the blood tubing. (Do not tie a knot in one end of the double spikes.)

8.8 The physician will spike product with blood set, making sure that the seal is closed between the saline rinse bag and product bag. The physician will open the saline rinse bag and instill a portion of the normal saline (based on patient's weight) to rinse the bag ensuring all cells will be infused.

8.9 If the product is in a syringe, place the 60mL syringe containing UCB product into the Syringe Pump. The Alaris syringe pump is illustrated below.
8.10 The physician will start an IV if needed and give patient Benadryl and steroids to prevent infusion-related reactions.

8.11 The cord blood cells will be infused over 5 to 25 minutes.

8.12 If the product is in a bag, the IV Fluids will be connected to the patient’s IV and infused at the rate determined by the Nurse Practitioner. If the product is in a syringe, the IV Fluids will be connected to the stopcock on the syringe. After infusing the cells from the syringe, turn the stopcock off to the 60mL syringe and infuse the IV Fluids at the rate determined by the Nurse Practitioner.

8.13 The Nurse Clinician will obtain and record vital signs q5mins for 15mins or until the infusion is complete.

8.14 The Nurse Clinician will document infusion on the SCTL-SOP-050 Infusion Form. PBMT Nurse Clinician will also document heart rate and O2 saturations, times of medications and cord blood infusion into EPIC.

8.15 The Nurse Clinician will document any adverse experiences during the infusion or within the 24 hour time period following the infusion on form STCL-GEN-050 Infusion Form. Once form STCL-GEN-050 Infusion Form is complete, the nurse clinician will fax the form to the SCTL for inclusion in the patients STCL file.

8.16 Maintain documents per hospital policy.

9 RELATED DOCUMENTS/FORMS

9.1 STCL-SOP-050 Infusion Form

10 REFERENCE


11 REVISION HISTORY

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<td>J. Sun.</td>
<td>Update to include use of syringe for administration of product.</td>
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<td>J. Kurtzberg</td>
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# Signature Manifest

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All dates and times are in Eastern Time.

## PBMT-GEN-060

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