



PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

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Bone Marrow Harvest Procedure

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PBMT-COLL-008

BONE MARROW HARVEST PROCEDURE

1 PURPOSE

- 1.1 Bone marrow is harvested in the operative suite and used for bone marrow rescue following myeloablative or non-myeloablative therapy in the treatment of a variety of malignancies or other transplantable diseases.
- 1.2 In both adult and pediatric patients, the bone marrow harvest is performed as a sterile procedure which consists of multiple bone marrow aspirations from the posterior iliac bones while the patient is under general or spinal anesthesia. The secondary sites for harvest are the anterior iliac crests.

2 INTRODUCTION

- 2.1 Bone marrow is aspirated using bone marrow aspiration needles and is collected in heparinized plasma-lyte. The bone marrow is filtered through 850 micron, 500 micron and 200 micron screens in a closed system to remove fat, bone spicules, and micro-clots, and collected in a transfer pack which is either transported to the Stem Cell Laboratory (STCL) for processing or if processing is not required then a quality control (QC) sample is sent to the STCL and the marrow is delivered directly to the recipient's bedside for infusion.

3 SCOPE AND RESPONSIBILITIES

- 3.1 Bone marrow is harvested by a bone marrow transplant attending physician who is assisted by an advanced practice provider (APP), fellow or second attending.
- 3.2 Anesthesia is administered under the direction of a licensed adult or pediatric anesthesiologist.
- 3.3 Training will be completed prior to staff performing independently on this Standard Operating Procedure.

4 DEFINITIONS/ACRONYMS

- 4.1 APP Advanced Practice Provider
- 4.2 Kg Kilogram
- 4.3 mL Milliliter
- 4.4 PPE Personal Protective Equipment
- 4.5 QC Quality Control
- 4.6 STCL Stem Cell Laboratory
- 4.7 SOP Standard Operating Procedure

5 MATERIALS

- 5.1 Stem Cell Laboratory
 - 5.1.1 Plasma-lyte A Injection - 500 mL bags - Baxter, Product # 2B2543

- 5.1.2 Validated transport container (cooler)
- 5.1.3 Labels as provided by the STCL

6 EQUIPMENT

- 6.1 Hospital-supplied equipment, including that in the operating room, is maintained in accordance with hospital policy and in accordance with applicable law. (See related policies: *DUHS Clinical Engineering Policy Inspection of Patient Related Equipment*; and DUH Policy: *Operating Room Cleanliness*.)
- 6.2 Operating Room (sterile)
 - 6.2.1 Prep table
 - 6.2.2 Prep kit
 - 6.2.3 Heparin 1,000 units/mL – 2 mL vials preservative free; number of vials depending on the projected harvest volume
 - 6.2.4 Four Sterile towels for drape
 - 6.2.5 Light handles
 - 6.2.6 LEE-LOK bone marrow aspirate needles:
 - 6.2.6.1 11 gauge 4 inch
 - 6.2.6.2 13 gauge 4 inch
 - 6.2.6.3 15 gauge 2 inch
 - 6.2.6.4 20 gauge 1.5 inch
 - 6.2.7 Luer tip syringes:
 - 6.2.7.1 Six 20 mL (DUMC Mat Mgmt (B-D))
 - 6.2.7.2 Four 10 mL (DUMC Mat Mgmt (B-D))
 - 6.2.8 Case Cart
 - 6.2.9 Bio Access Bone Marrow Collection System (Item #MH-2150)
 - 6.2.10 Scissors, 1 ea.
 - 6.2.11 One 3mL Luer tip syringe (DUMC Mat Mgmt (B-D))
 - 6.2.12 Towels
 - 6.2.13 Sponge, dressing
 - 6.2.14 Gloves (DUMC Materials Management)
 - 6.2.15 Surgical packs
 - 6.2.16 Breast/chest sheet
 - 6.2.17 Custom Basic pack
 - 6.2.18 Basic linen pack

7 SAFETY

- 7.1 Follow all safety-related standard operating procedures (SOPs) and wear all necessary personal protective equipment (PPE) when handling potentially hazardous blood and body fluids to include, but not limited to, gloves, lab coats, scrubs, masks, goggles, and face shields. (see related DUHS policies: *DUHS Standard & Transmission-based Precautions*; and *DUHS Hand Hygiene*)
- 7.2 Medical and biohazard waste will be disposed of in accordance with institutional policy and procedure (See www.safety.duke.edu for full listing of safety procedures).

8 PROCEDURE

8.1 Initial Patient Evaluation (For Autologous Donors)

8.1.1 Bone marrow evaluation

- 8.1.1.1 Bone marrow aspirates and core biopsies as per clinical indication by diagnosis

8.1.2 Evaluation for visceral disease as indicated

- 8.1.2.1 CT scan chest, abdomen, pelvis
- 8.1.2.2 CT scan brain

8.1.3 Histologic confirmation of disease

- 8.1.3.1 Original tumor, pathology slides or blocks, and report
- 8.1.3.2 Metastatic lesion(s), pathology slides or blocks, and report (patients with metastatic disease)

8.1.4 Major organ function

8.1.4.1 Pulmonary

- 8.1.4.1.1 Age appropriate pulmonary function test

8.1.4.2 Cardiac

- 8.1.4.2.1 Ventricular function
- 8.1.4.2.2 EKG (protocol specific)

8.1.4.3 Renal

- 8.1.4.3.1 Serum creatinine, GFR or creatinine clearance

8.1.4.4 Hepatic

- 8.1.4.4.1 Liver function tests

8.1.5 Completion of the following laboratory studies

8.1.5.1 Hematologic

- 8.1.5.1.1 Complete blood count, differential, including platelets and coagulation panel.

8.1.5.2 Chemistries

- 8.1.5.2.1 Serum electrolytes

- 8.1.5.2.2 Total protein, albumin, calcium, phosphorus, uric acid, magnesium
 - 8.1.5.3 Infection Disease Markers
 - 8.1.5.3.1 Donor referral NTL panel, age specific as applicable.
 - 8.1.5.3.2 VZV IgG AB
 - 8.1.5.3.3 HSV IgG AB
 - 8.1.5.3.4 Toxoplasma gondii IgG & IgM AB
 - 8.1.5.3.5 EBV AB

NOTE: Additional markers may be performed according to CDC recommendations.
 - 8.1.5.4 Pregnancy test, serum beta-HCG, rapid (female patients of appropriate age). For more extensive details regarding pregnancy testing, including timing requirements, see related document APBMT-COMM-001 *Donor Selection, Evaluation, and Management*.
 - 8.1.5.5 Tumor markers, if applicable
- 8.2 Patient (Autologous or Allogeneic Donor) Preparation

NOTE: Donors should begin iron supplementation from initial assessment and continue until approximately 2 months post-harvest procedure, as clinically applicable and necessary.

 - 8.2.1 Immediate pre-operative screening
 - 8.2.1.1 Pre-operative screening includes an overall assessment of donor suitability immediately prior to the harvest procedure.
 - 8.2.1.2 Donor suitability will be documented in the EMR by the attending physician and verified by the team performing the harvest collection prior to the collection procedure.
 - 8.2.2 Completion of the following laboratory studies
 - 8.2.2.1 Complete blood counts with differential platelets
 - 8.2.2.2 Coagulation studies: PT, PTT
 - 8.2.2.3 Serum electrolytes
 - 8.2.2.4 Type and screen
 - 8.2.2.5 Consider U/A
 - 8.2.2.6 Infection Disease Markers
 - 8.2.2.6.1 Donor Screening Tests as outlined in APBMT-COMM-001 *Donor Selection, Evaluation and Management* and APBMT-COMM-001

FRM2 Summary of Donor Eligibility and Infectious Disease Testing (PBMT) FRM2

8.2.2.6.2 VZV IgG AB

8.2.2.6.3 HSV IgG AB

8.2.2.6.4 Toxoplasma gondii IgG & IgM AB

8.2.2.6.5 EBV AB

NOTE: Additional markers may be performed according to CDC recommendations.

8.2.2.7 Other pre-operative tests and preparations

8.2.2.7.1 EKG

8.2.2.7.2 Anesthesia evaluation

8.2.2.7.3 NPO after midnight

8.3 Verification of informed consent will occur prior to the initiation of the harvest procedure. Informed consent will be obtained from all donors prior to the harvest procedure and will contain the following elements at a minimum:

8.3.1 Nature and purpose of the procedure and any additional associated tests, explained in terms the donor can understand

8.3.1.1 Including tests and procedures performed to protect the health of the donor and the recipient.

8.3.1.2 The rights of the donor to review results according to applicable law.

8.3.2 Multiple aspirations as a method of procuring marrow

8.3.3 Potential benefit(s)

8.3.4 Potential risks

8.3.5 Anesthesia

8.3.6 Pain

8.3.7 Injury to bone and/or nerve

8.3.8 Infection

8.3.9 Blood loss

8.3.10 Decreased blood pressure

8.3.11 Hypovolemic shock

8.3.12 Death

8.3.13 Intent of the collection for research, if applicable

8.3.14 Protection of medical information and confidentiality

- 8.3.15 For additional information regarding the consenting process, see related policy PBMT-GEN-059 *Autologous and Allogeneic Donor Consenting Procedure*.

8.4 Bone Marrow Harvest

NOTE: Gloves and protective clothing will be worn as required by hospital and/or location policy, as applicable, and at a minimum while handling biological specimens. Such PPE items will be removed before leaving the harvest collection area and as required by policy.

8.4.1 Verify Harvest Volume:

8.4.1.1 Confirm requested collection TNC goal. Use average TNC of 18.7×10^6 cells/mL to calculate volume need.

8.4.1.2 Verify volume requested does not surpass recommended maximum collection. The goal is to avoid collecting more than 20ml/kg (pediatric) or 1500mL (adult) total unless approved by medical director on select cases.

8.4.2 Estimate Possible Blood Loss: *See reference for example*

8.4.2.1 Estimated total blood volume (mL) = Wt (kg) \times (70 for female, 75 for male)

8.4.2.2 Baseline RBC volume (mL) = Estimated total blood volume \times Pt Hct

8.4.2.3 Harvest RBC loss (mL) = Harvest volume \times RBC content in BM product (i.e., assume BM 30% Hct)

8.4.2.4 Estimated soft tissue RBC loss (mL) = (Harvest volume \times 0.3) \times Pt Hct

8.4.2.5 Total RBC loss (mL) = Harvest RBC loss + Soft tissue RBC loss

8.4.2.6 Estimated post-harvest Hct (%) = (Baseline RBC volume – Total RBC loss) / Total blood volume

8.4.3 Blood Product Availability:

8.4.3.1 Ensure autologous or CMV-appropriate and irradiated blood components are readily available should use be required during the marrow collection procedure.

8.4.3.2 If required, ensure allogeneic blood products used during the marrow collection procedure are CMV-appropriate and irradiated (or equivalent) prior to transfusion.

8.4.4 Visually inspect each supply and/or reagent to be used during collection prior to use for damage or evidence of contamination and outdates. If any signs of either are noted, discard and replace. Should a staff member involved in the harvesting processes note that a piece of equipment (or supply/reagent) is non-functional, expired, found to be out of calibration or specification, or simply unable to be utilized and

without an immediate available replacement, the staff member will contact a member of OR management and/or quality management for determination of next steps in accordance with internal processes and procedures.

8.4.5 Preparation of Plasma-lyte for use

- 8.4.5.1 Add 4 mL of 1,000 unit/mL preservative free heparin to 100 mL of Plasma-lyte A Injection media in a sterile container.
- 8.4.5.2 Transfer 40 mL of the 104 mL solution into the collection bag and 64 mL into the anticoagulation bag.
- 8.4.5.3 Flush both the anticoagulation bag valve and the collection bag valve with 1 mL of the 1,000 unit/mL preservative free heparin and inject it into respective bags.
- 8.4.5.4 Attach a syringe with a predetermined volume of 1,000 unit/mL preservative free heparin to the stopcock on the top of the collection bag. The predetermined amount of heparin will be at least 1 mL/100 mL of planned harvest product.

8.4.6 Harvest

- 8.4.6.1 Induce anesthesia
 - 8.4.6.1.1 Remind the anesthesia team to not administer corticosteroid drugs until the collection has been completed.
 - 8.4.6.1.2 Indicate that intraoperative antibiotic drugs are not routinely required
- 8.4.6.2 Encourage avoidance of nonsteroidal anti-inflammatory drugs (e.g., Ketorolac), to avoid postoperative bleeding.
- 8.4.6.3 Call a time out.
- 8.4.6.4 Select the site of aspiration.
 - 8.4.6.4.1 posterior iliac bone
 - 8.4.6.4.2 anterior iliac crests
 - 8.4.6.4.3 sternum
- 8.4.6.5 Position patient.
 - 8.4.6.5.1 Prepare operative field with prep regimen.
 - 8.4.6.5.2 Drape field with sterile towels and breast/chest sheet.
 - 8.4.6.5.3 Hold the aspirate needle with the flat of the trocar in the palm of the hand, and the shaft of the needle between the thumb and fingers of the hand. Direct the needle through the skin to the surface of the bone, keeping the needle perpendicular to the plane of the surface of the

- bone. For Pediatric patients weighing under 10 kgs, 20 gauge spinal needles may be used.
- 8.4.6.5.4 Advance the needle through the outer plate of the bone, using a gentle but firm twisting motion.
- 8.4.6.5.5 When the needle is firmly seated in the marrow cavity, remove the trocar from the needle.
- 8.4.6.5.6 Attach a 10 mL or 20 mL syringe to the needle and aspirate 5-15 mL over 20-30 seconds, while rotating the needle in the bone so that the bevel of the needle is continually exposed to an unaspirated portion of the marrow space.
- 8.4.6.5.7 When the aspiration is completed, grasp the syringe and twist/remove from the needle.
- 8.4.6.5.8 Hand the syringe to the scrub nurse.
- 8.4.6.5.9 Place the trocar back and remove the needle from the bone or advance the needle to new marrow spaces and repeat as above.
- 8.4.6.5.10 Repeat the aspirate procedure, using the same skin entry site for multiple entries into the bone while avoiding a pre-aspirated site.
- 8.4.7 Scrub Nurse procedure
 - 8.4.7.1 When handed a syringe of marrow, attach the syringe to the collection bag Luer lock, un-clamp the stop cock to the collection bag & depress the TRAC valve. Then inject the marrow into the collection bag. Following this injection into the collection bag, depress the TRAC valve to the anticoagulation bag and aspirate the anticoagulation into the syringe, flushing back and forth twice to fully rinse. Remove the syringe from the Luer lock and repeat the procedure with next syringe containing marrow.
 - 8.4.7.2 For each 100 mL of marrow collected in the collection bag, inject 1 mL of the 1,000 unit/mL heparin. With the exception that when you reach increments of 500 mL collection volumes.
 - 8.4.7.2.1 For each 500 mL of bone marrow harvested, add 2 mL of additional 1,000 unit/mL preservative free heparin to the collection bag.
 - 8.4.7.3 The scrub nurse should gently massage the collection bag at least every 5 minutes.

- 8.4.7.4 A PTCT RN coordinator will be present when available during the harvest to document volume total by syringe.
- 8.4.7.5 Based on pre-planned marrow volume, complete the harvest.
NOTE: Donor safety is paramount, and the bone marrow harvest procedure may be discontinued at the attending physician's discretion if the minimum volume of marrow planned for cannot be aspirated.

8.5 Post-harvest

- 8.5.1 Sterilely attach 850 micron, 500 micron and 200 micron triple filter set up to the bone marrow collection bag. Sterilely attach the appropriate transfer bag (2000 mL or 600 mL) to the bottom of the filter set.
- 8.5.2 Sterilely open clamps to allow the marrow to flow from the bone marrow collection bag through the 850 micron, 500 micron and 200 micron filters into the transfer bag, utilizing gravity flow. If a QC sample is required, sterilely obtain 10 mLs from the transfer bag and send to the STCL.
- 8.5.3 When the marrow is filtered into the transfer bag, sterilely close the clamp on the transfer pack, and tie a knot in the tubing below the clamp. Sterilely place a cap over the end of the tubing.
- 8.5.4 Labeling:

NOTE: At all times labeling processes will be conducted in a manner to prevent mislabeling or misidentification of samples and during all stages of the collection process, samples will remain labeled with product name and a unique identifier as outlines below.

NOTE: Labels applied to the harvested product include warning instructions stating: "Do Not Irradiate". Products may undergo additional labeling processes in the processing facility (STCL) when required and are outlined in laboratory procedures.

- 8.5.4.1 Labeling at the end of collection will occur before the collection product bag is removed from the proximity of the donor.
 - 8.5.4.1.1 This step will include donor identification verified against the label information, prior to removing the product from the proximity of the donor.
- 8.5.4.2 Label all samples using the labels provided. When possible, ensure a sufficient area of the container remains unobstructed to permit inspection of the contents.
 - 8.5.4.2.1 On demand product label containing ISBT identification number.
 - 8.5.4.2.2 Attach patient identification labels to bag containing bone marrow

- 8.5.4.2.3 Verify labels are attached securely and processes were performed accurately.
 - 8.5.5 Dressing the operative sites
 - 8.5.5.1 Clean operative site with warm sterile saline and dry thoroughly.
 - 8.5.5.2 Apply sterile dressings and secure with a pressure dressing.
 - 8.5.5.3 Reverse anesthesia and transport the patient to Post-Anesthesia Care Unit.
- 8.6 Transport of product to STCL
 - 8.6.1 Place the bone marrow-filled transfer pack in the designated transport container (cooler) for transport to the STCL in a temperature-controlled vehicle to ensure the internal temperature of the cooler (and product) is maintained while traveling to the STCL on public roads.
 - 8.6.2 The following paperwork must accompany the product
 - 8.6.2.1 APBMT-COMM-001 FRM2 *Summary of Donor Eligibility and Infectious Disease Testing (PBMT) FRM2*
 - 8.6.2.2 STCL-SOP-050 *Infusion Form*
 - 8.6.2.3 STCL-FORM-037 *Bone Marrow Harvest Quality Assurance Sheet*
 - 8.6.2.4 STCL-FORM-056 *Cellular Therapy Infusion Request Form (if applicable)*
 - 8.6.2.5 STCL-FORM-062 *Stem Cell Laboratory Processing Order Form (if applicable)*
 - 8.6.3 Fill out location related information found on the “Cellular Product Distribution Form for Cooler” located on the outside of transport container. (See STCL-FORM-042 *Cellular Product Distribution Form for Cooler* for a complete view of information.)
- 8.7 Transport of product to clinical unit
 - 8.7.1 Place the bone marrow-filled transfer pack and QC and / or research syringes in the designated transport container (cooler) for transport the bone marrow to the clinical unit. Once the bone marrow is delivered, the cooler, containing the QC and any research samples, is then transported to the STCL in a temperature-controlled vehicle to ensure the internal temperature of the cooler (and product) is maintained while traveling to the STCL on public roads.
 - 8.7.2 The following paperwork must accompany the product
 - 8.7.2.1 APBMT-COMM-001 FRM2 *Summary of Donor Eligibility and Infectious Disease Testing (PBMT) FRM2*
 - 8.7.2.2 STCL-SOP-050 *Infusion Form*

- 8.7.2.3 STCL-FORM-037 *Bone Marrow Harvest Quality Assurance Sheet*
- 8.7.2.4 STCL-FORM-056 *Cellular Therapy Infusion Request Form (if applicable)*
- 8.7.2.5 STCL-FORM-062 *Stem Cell Laboratory Processing Order Form (if applicable)*
- 8.7.3 Fill out location related information found on the “Cellular Product Distribution Form for Cooler” located on the outside of transport container. (See STCL-FORM-042 *Cellular Product Distribution Form for Cooler* for a complete view of information.)
- 8.8 Documentation in electronic medical record following completion of procedure in accordance with FACT compliance. Smartphrase that can be used .PBMTBONEMARROWHARVEST.

9 RELATED FORMS/DOCUMENTS

- 9.1 APBMT-COMM-001 Donor Selection, Evaluation, and Management
- 9.2 APBMT-COMM-001 FRM2 Summary of Donor Eligibility and Infectious Disease Testing (PBMT) FRM2
- 9.3 PBMT-GEN-059 Autologous and Allogeneic Donor Consenting Procedure
- 9.4 STCL-SOP-050 Infusion Form
- 9.5 STCL-FORM-037 Bone Marrow Harvest Quality Assurance Sheet
- 9.6 STCL-FORM-042 Cellular Product Distribution Form for Cooler
- 9.7 STCL-FORM-056 Cellular Therapy Infusion Request Form
- 9.8 STCL-FORM-062 Stem Cell Laboratory Processing Order Form (if applicable)
- 9.9 DUHS policy: DUHS Standard & Transmission-based Precautions
- 9.10 DUHS Policy: DUHS Hand Hygiene
- 9.11 DUHS policy: DUHS Clinical Engineering Policy Inspection of Patient Related Equipment
- 9.12 DUH Policy: Operating Room Cleanliness

10 REFERENCES

- 10.1 Internal procedure for Duke University Medical Center Autologous Bone Marrow Transplant Program.
- 10.2 Bone Marrow Harvest: A White Paper of Best Practices by the NMDP Marrow Alliance. Murakami, Mark A. et al. Transplantation and Cellular Therapy, Official Publication of the American Society for Transplantation and Cellular Therapy, Volume 30, Issue 7, 663 – 680.

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
15	MC Author: S. McCollum SME: Erika Summers Goekerman Brittany DePriest	Section 6.2.7 update to remove materials no longer utilized. Section 8.2.2 updated for urinalysis consideration (no longer required) Section 8.4.1 updated for steps in verification of harvest volumes as best practice Section 8.4.2 update for steps to estimate blood loss as best practice Section 8.4.6 updated with medication reminders for corticosteroids, antibiotics, and NSAIDS Section 8.4.6 updated to reduce syringe and aspiration volumes to better reflect current practice Section 8.4.7 added addition of PTCT RN coordinator during harvest Section 8.7 updated to include smartphrase documentation tools to help standardize documentation Section 10 additional references included to bring more current

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PBMT-COLL-008 Bone Marrow Harvest Procedure**Author**

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Bing Shen (BS76)	Associate Director, Quality Assurance	28 May 2025, 01:50:06 PM	Approved

Document Release

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Amy McKoy (ACM93)	Document Control Specialist	29 May 2025, 09:51:49 AM	Approved