# Document Information

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CONFIDENTIAL - Printed by: ACM93 on 06 Nov 2019 08:11:33 am
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. 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 is 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.

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. Anesthesia is administered under the direction of a licensed adult or pediatric anesthesiologist.

3.2 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)
6  EQUIPMENT

6.1  Operating Room (sterile)
   6.1.1  Prep table
   6.1.2  Prep kit
   6.1.3  Heparin 1,000 units/mL – 2 mL vials preservative free; number of vials depending on the projected harvest volume
   6.1.4  Four Sterile towels for drape
   6.1.5  Light handles
   6.1.6  LEE-LOK bone marrow aspirate needles:
       6.1.6.1  11 gauge 4 inch
       6.1.6.2  13 gauge 4 inch
       6.1.6.3  15 gauge 2 inch
       6.1.6.4  20 gauge 1.5 inch
   6.1.7  Luer tip syringes:
       6.1.7.1  Six 20mL  DUMC Mat Mgmt (B-D)
       6.1.7.2  Six 60mL  DUMC Mat Mgmt (B-D)
   6.1.8  Case Cart
   6.1.9  Bio Access Bone Marrow Collection System
   6.1.10 Scissors, 1 ea
   6.1.11 One 3mL Luer tip syringe  DUMC Mat Mgmt (B-D)
   6.1.12 Towels
   6.1.13 Sponge, dressing
   6.1.14 Gloves  DUMC Materials Management
   6.1.15 Surgical packs
   6.1.16 Breast/chest sheet
   6.1.17 Custom Basic pack
   6.1.18 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.

8  PROCEDURE

8.1  Initial Patient Evaluation (For Autologous Donors)
8.1.1 Bone marrow evaluation
8.1.1.1 Bilateral bone marrow aspirates and core biopsies

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)
8.1.5.5 Tumor markers, if applicable

8.2 Patient- Autologous or Allogeneic Donor Preparation

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 Urinalysis, clean catch (adults only)
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 Chest x-ray
8.2.2.7.2 EKG (for adults only)
8.2.2.7.3 Anesthesia evaluation
8.2.2.7.4 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 procedure
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

8.4 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 Blood Product Availability:
8.4.1.1 Ensure autologous or CMV-appropriate and irradiated blood components are readily available should use be required during the marrow collection procedure.
8.4.1.2 If required, ensure allogeneic blood products used during the marrow collection procedure are irradiated prior to transfusion.

8.4.2 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.

8.4.3 Preparation of Plasma-lyte for use
8.4.3.1 Add 4 mL of 1,000 unit/mL preservative free heparin to 100 mL of Plasma-lyte A Injection media directly into anticoagulation bag.
8.4.3.2 Transfer 40 mL of the 104 mL solution into the collection bag leaving 64 mL in the anticoagulation bag.
8.4.3.3 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.
8.4.3.4 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.

8.4.4 Harvest

8.4.4.1 Induce anesthesia

8.4.4.2 Call a time out.

8.4.4.3 Select the site of aspiration.

8.4.4.3.1 posterior iliac bone

8.4.4.3.2 anterior iliac crests

8.4.4.3.3 sternum

8.4.4.4 Position patient.

8.4.4.4.1 Prepare operative field with prep regimen.

8.4.4.4.2 Drape field with sterile towels and breast/chest sheet.

8.4.4.4.3 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.

8.4.4.4.4 Advance the needle through the outer plate of the bone, using a gentle but firm twisting motion.

8.4.4.4.5 When the needle is firmly seated in the marrow cavity, remove the trocar from the needle.

8.4.4.4.6 Attach a 10 mL, 20 mL or 60 mL Luer-tip syringe to the needle and aspirate 5-20 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.

8.4.4.4.7 When the aspiration is completed, grasp the syringe and twist/remove from the needle.

8.4.4.4.8 Hand the syringe to the scrub nurse.

8.4.4.4.9 Place the trocar back and remove the needle from the bone or advance the needle to new marrow spaces and repeat as above.
8.4.4.10 Repeat the aspirate procedure, using the same skin entry site for multiple entries into the bone while avoiding a pre-aspirated site.

8.4.5 Scrub Nurse procedure
8.4.5.1 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.

8.4.5.2 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.

8.4.5.2.1 For each 500 mL of bone marrow harvested, add 2 mL of additional 1,000 unit/mL preservative free heparin to the collection bag.

8.4.5.3 The scrub nurse should gently massage the collection bag every 5 minutes.

8.4.5.4 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 10mLs 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.

8.5.4.2 Label the bone marrow using the provided labels. 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.

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

8.6.3 Fill out Cellular Product Distribution Form for Cooler located on the outside of transport container.
8.7 Transport of product to Clinical unit

8.7.1 Place the bone marrow-filled transfer pack and research syringe(s) 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 research sample, is then transported to the STCL.

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

8.7.3 Fill out Cellular Product Distribution Form for Cooler located on the outside of transport container.
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 STCL-SOP-050 Infusion Form
9.4 STCL-FORM-037 Bone Marrow Harvest Quality Assurance Sheet

10 REFERENCES
10.1 Internal procedure for Duke University Medical Center Autologous Bone Marrow Transplant Program.

11 REVISION HISTORY

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<th>Description of Change(s)</th>
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<tr>
<td>11</td>
<td>S. McCollum</td>
<td>- Equipment Section: updated to include: “20 gauge 1.5 inch” for infant collections</td>
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<td>- Section 8.2.1: added to clarify role of donor suitability verification and documentation by attending physician.</td>
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<td>- Section 8.4: “NOTE” sections added</td>
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<td>- Section 8.5.4: language inserted to support workflow around labeling processes</td>
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<tr>
<td></td>
<td></td>
<td>- Section 8.6.2 and 8.7.2: formal names for paperwork inserted.</td>
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<td>- Related Documents Section: updated to include additional documents referenced in this document.</td>
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<td>- Section 8: duplicate information removed throughout</td>
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# PBMT-COLL-008 Bone Marrow Harvest Procedure

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## Medical Director

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