# 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. 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 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 a nurse practitioner, 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 Kg kilogram
4.2 mL milliliter
4.3 PPE Personal Protective Equipment
4.4 QC Quality Control
4.5 STCL Stem Cell Laboratory
4.6 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
6.1.7 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 Mat Mgmt
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 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
Tumor markers, if applicable

Pregnancy test, serum beta-HCG, rapid (female patients only)

Recommendations:

Additional markers may be performed according to CDC

NOTE: Additional markers may be performed according to CDC

EBV AB

Toxo IgG & IgM AB

HSV IgG AB

AZV IgG AB

Donor referral NTL panel

Infection Disease Markers

ELISA, measles

Total protein, albumin, calcium, phosphorus

Serum electrolytes

Chemistries

Complete blood count including platelets

Hematologic

Complete laboratory studies

Liver function tests

Serum creatinine, GFR, or creatinine clearance

Electrocardiograph (protocol specific)

Ventilatory function test

Pulmonary function test

Major organ function

Patients with metastatic disease

Metastatic lesion(s), pathologic slides or blocks, and report

Original tumor, pathologic slides or blocks, and report

Histologic confirmation of disease

CT scan brain
8.2 Patient- Autologous or Allogeneic Donor Preparation

8.2.1 Immediate pre-operative screening

8.2.2 Laboratory studies

8.2.2.1 Complete blood counts, 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 referral NTL panel

8.2.2.6.2 VZV IgG AB

8.2.2.6.3 HSV IgG AB

8.2.2.6.4 Toxo 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 Informed consent

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

8.4.1 Blood Product Availability:

8.4.1.1 Ensure autologous or CMV-appropriate and irradiated blood components are readily available should 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. 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 Add 1 mL of heparin into the collection bag for each 500 mL of bone marrow collected.

8.4.3.5 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 1mL/100mL 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.
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.

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

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

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.

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

Hand the syringe to the scrub nurse.

Place the trocar back and remove the needle from the bone.

Repeat the aspirate procedure, using the same skin entry site for multiple entries into the bone while avoiding a pre-aspirated site.

**Scrub Nurse procedure**

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.

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, add a total of 2 mL.

The scrub RN should gently massage the collection bag every 5 minutes.
For each 500 mL of bone marrow harvested, add 2 mL of additional 1,000 unit/mL preservative free heparin to the collection bag.

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, steriley obtain 10mLs from the transfer bag and send to the STCL.

8.5.3 When the marrow is filtered into the transfer bag, steriley 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 Label the bone marrow using the provided labels

8.5.4.1 On demand product label containing ISBT identification number

8.5.4.2 Attach patient identification labels to bag containing bone marrow

8.5.4.3 Labeling at the end of collection will occur before the collection product bag is removed from the proximity of the donor.

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 Donor Summary of Eligibility

8.6.2.2 Infusion orders
8.6.2.3 BMH Quality Assurance Form

8.6.3 Fill out Cellular Product Distribution Form for Cooler located on the outside of transport container.

Cellular Product Distribution Form for Cooler: [Check ONE]

- [ ] NS100, Duke North Hospital, Erwin Road, Durham, NC 27705 (5th Floor)
  Contact Person: Charge Nurse
  Phone #: 919-681-5141

- [ ] NS200, Duke North Hospital, Erwin Road, Durham, NC 27705 (5th Floor)
  Contact Person: Charge Nurse
  Phone #: 919-681-5241

- [ ] NS200, Duke North Hospital, Erwin Road, Durham, NC 27705 (9th Floor)
  Contact Person: Charge Nurse
  Phone #: 919-681-9241

- [ ] CHC, Children's Health Center, Erwin Road, Durham, NC 27705 (4th Floor)
  Contact Person: Charge Nurse
  Phone #: 919-681-4490

- [ ] ABMT Clinic, 2400 Pratt Street, Suite 1100, Durham, NC 27705
  Contact Person: Charge Nurse
  Phone #: 919-681-9241

- [ ] Other Location's Address: ________________________________
  Contact Person's Name: ________________________________
  Phone #: ________________________________

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 Donor Summary of Eligibility

8.7.2.2 Infusion orders,

8.7.2.3 BMH Quality Assurance Form

8.7.3 Fill out Cellular Product Distribution Form for Cooler located on the outside of transport container.

Cellular Product Distribution Form for Cooler: [Check ONE]

- [ ] NS100, Duke North Hospital, Erwin Road, Durham, NC 27705 (5th Floor)
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  Phone #: 919-681-5141

- [ ] NS200, Duke North Hospital, Erwin Road, Durham, NC 27705 (5th Floor)
  Contact Person: Charge Nurse
  Phone #: 919-681-5241

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  Phone #: 919-681-4490

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  Contact Person: Charge Nurse
  Phone #: 919-681-9241

- [ ] Other Location's Address: ________________________________
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  Phone #: ________________________________
9 RELATED FORMS/DOCUMENTS

9.1 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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<td>Section 8.4.5.2 updated to define Scrub Nurse Responsibility and volume: 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, add a total of 2 mL.</td>
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All dates and times are in Eastern Time.

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