**DOCUMENT NUMBER:** ABMT-COLL-017  

**DOCUMENT TITLE:**  
Bone Marrow Harvest Procedure

**DOCUMENT NOTES:**  
7C.102 v 02

**Document Information**

<table>
<thead>
<tr>
<th>Revision:</th>
<th>06</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vault:</td>
<td>ABMT-Collections-re1</td>
</tr>
<tr>
<td>Status:</td>
<td>Release</td>
</tr>
<tr>
<td>Document Type:</td>
<td>Collections</td>
</tr>
</tbody>
</table>

**Date Information**

<table>
<thead>
<tr>
<th>Creation Date:</th>
<th>30 Jul 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Release Date:</td>
<td>15 Aug 2018</td>
</tr>
<tr>
<td>Effective Date:</td>
<td>15 Aug 2018</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
</tr>
</tbody>
</table>

**Control Information**

<table>
<thead>
<tr>
<th>Author:</th>
<th>JLF29</th>
</tr>
</thead>
<tbody>
<tr>
<td>Owner:</td>
<td>MC363</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Previous Number:</th>
<th>ABMT-COLL-017 Rev 05</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change Number:</td>
<td>ABMT-CCR-211</td>
</tr>
</tbody>
</table>

CONFIDENTIAL - Printed by: BJ42 on 15 Aug 2018 07:51:37 am
ABMT-COLL-017
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. The bone marrow harvest is performed as a sterile procedure and consists of multiple bone marrow aspirations from the posterior iliac bones while the patient is under general or spinal anesthesia.

2 INTRODUCTION
2.1 Bone marrow is aspirated using bone marrow aspiration needles and is collected in heparinized Plasma-lyte A solution. The maximum volume of bone marrow to be collected from a patient or donor is 20mL/kg. 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 transported to the Stem Cell Laboratory (STCL) for processing.

3 SCOPE AND RESPONSIBILITIES
3.1 Bone marrow is harvested by a bone marrow transplant attending physician, who is assisted by a nurse practitioner, physician assistant, fellow, or second attending. Anesthesia is administered under the direction of a licensed adult anesthesiologist.

4 DEFINITIONS/ACRONYMS
4.1 STCL Stem Cell Laboratory
4.2 SOPs Standard Operating Procedures
4.3 PPE Personal Protective Equipment
4.4 kgs kilograms
4.5 QC Quality Control
4.6 mls milliliters
4.7 DUMC Duke University Medical Center
4.8 Mat Mgmt. Materials Management

5 MATERIALS
5.1 Stem Cell Laboratory
5.2 Supply kit (pre-stocked)
5.3 Syringes, 5 cc Luer-tip DUMC Mat Mgmt. (B-D)
5.4 Syringes, 10 cc Luer-tip DUMC Mat Mgmt. (B-D)
5.5 Needle, 19 g, 1½”
5.6 Heparin, preservative free
5.7 5,000 units/ml, 10ml vials
5.8 Plasma-lyte A Injection - 500ml bags

6 EQUIPMENT
6.1 Operating Room (sterile)
6.2 Prep table
6.3 Prep kit
6.4 Four Sterile towels for drape
6.5 Light handles
6.6 LEE-LOK bone marrow aspirate needles:
   6.7 11 gauge 4 inch
   6.8 13 gauge 4 inch
   6.9 15 gauge 2 inch
6.10 Luer tip syringes
6.11 Six 20cc
6.12 Six 60 cc
6.13 Case Cart
6.14 Bio Access Bone Marrow Collection System
6.15 Beaker, 600ml, 50ml
6.16 Scissors, 1 ea.
6.17 One 3cc Luer tip syringe
6.18 Towels
6.19 Sponge, dressing
6.20 Gloves
6.21 Surgical packs
6.22 Breast/chest sheet
6.23 Custom Basic pack
6.24 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, surgical masks, goggles, face shields, etc.

8 PROCEDURE

8.1 Initial Patient Evaluation (For Autologous Donors)
  8.1.1 Bone marrow evaluation
    8.1.1.1 Bone marrow aspirate and core biopsy

8.2 Evaluation for visceral disease as indicated
  8.2.1 CT scan chest, abdomen, pelvis
  8.2.2 CT scan brain

8.3 Histologic confirmation of disease
  8.3.1 Original tumor, pathology slides or blocks, and report
  8.3.2 Metastatic lesion(s), pathology slides or blocks, and report (patients with metastatic disease)

8.4 Major organ function
  8.4.1 Pulmonary
    8.4.1.1 Age appropriate pulmonary function test
  8.4.2 Cardiac
    8.4.2.1 Ventricular function
    8.4.2.2 EKG (protocol specific)
  8.4.3 Renal
    8.4.3.1 Serum creatinine, GFR or creatinine clearance
  8.4.4 Hepatic
    8.4.4.1 Liver function tests

8.4.5 Other laboratory studies
  8.4.5.1 Hematologic
    8.4.5.1.1 Complete blood count, including platelets
  8.4.5.2 Chemistries
    8.4.5.2.1 Serum electrolytes
    8.4.5.2.2 Total protein, albumin, calcium, phosphorus, uric acid, magnesium
  8.4.5.3 Viral titers
    8.4.5.3.1 Donor referral NTL panel
    8.4.5.3.2 VZV IgG AB
    8.4.5.3.3 HSV IgG AB
8.4.5.3.4  Toxo IgG & IgM AB
8.4.5.3.5  EBV AB
8.4.5.4  Pregnancy test, serum beta-HCG, rapid (female patients of appropriate age)
8.4.5.5  Tumor markers, if applicable

8.5  Patient- Autologous or Allogeneic Donor Preparation

8.5.1  Immediate pre-operative screening
8.5.2  Laboratory studies
8.5.2.1  Complete blood counts, platelets
8.5.2.2  Coagulation studies: PT, PTT
8.5.2.3  Serum electrolytes
8.5.2.4  Type and screen
8.5.2.5  Urinalysis, clean catch (adults only)
8.5.2.6  Viral titers
8.5.2.6.1  Donor referral NTL panel
8.5.2.6.2  VZV IgG AB
8.5.2.6.3  HSV IgG AB
8.5.2.6.4  Toxo IgG & IgM AB
8.5.2.6.5  EBV AB
8.5.2.7  Other pre-operative tests and preparations
8.5.2.7.1  Chest x-ray
8.5.2.7.2  EKG (for adults only)
8.5.2.7.3  Anesthesia evaluation
8.5.2.7.4  NPO after midnight
8.5.2.7.5  Anti-embolism stockings on adult patients, on-call to OR

8.6  Informed consent

8.6.1  Nature and purpose of procedure
8.6.2  Multiple aspirations as a method of procuring marrow
8.6.3  Potential benefit(s)
8.6.4  Potential risks
8.6.5  Anesthesia
8.6.6  Pain
8.6.7  Injury to bone and/or nerve
8.6.8 Blood loss
8.6.9 Decreased blood pressure
8.6.10 Hypovolemic shock
8.6.11 Death

8.7 Bone Marrow Harvest

8.7.1 Preparation of Plasma-lyte A solution:
  8.7.1.1 Add 10ml of 5,000 unit/ml preservative free heparin to 500ml of Plasma-lyte A Injection media in the Plasma-lyte A bag.
  8.7.1.2 Inject 100ml of the solution into the 600ml anticoagulation bag.
  8.7.1.3 Transfer 100ml of the solution into the 1,500ml collection bag.
  8.7.1.4 Flush all collection syringes with the heparin solution.

8.7.2 Autologous or CMV-appropriate and irradiated blood components shall be available during the marrow collection procedure for all donors

8.7.3 Allogeneic blood components administered to the donor during marrow collection should be irradiated prior to transfusion.

8.7.4 Harvest

8.7.4.1 Induce anesthesia
8.7.4.2 Call a time out.
8.7.4.3 Select the site of aspiration.
  8.7.4.3.1 Posterior iliac bone
  8.7.4.3.2 Anterior iliac crests and/or sternum
8.7.4.4 Position patient
  8.7.4.4.1 Prepare operative field with prep regimen.
  8.7.4.4.2 Drape field with sterile towels and breast/chest sheet.
  8.7.4.4.3 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.
  8.7.4.4.4 Advance the needle into the bone, using a gentle but firm twisting motion.
8.7.4.4.5 When the needle is firmly seated in the marrow cavity, remove the trocar from the needle.

8.7.4.4.6 Attach a 20cc Luer-tip syringe to the needle and aspirate 5-20ml 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.

8.7.4.4.7 When the aspiration is completed, remove the needle and syringe.

8.7.4.4.8 Detach the needle from the syringe and hand the syringe to the scrub nurse.

8.7.4.4.9 Place the trocar back into the needle.

8.7.4.4.10 Repeat the aspirate procedure, using the same skin incision site for multiple entries into the bone, in a clockwise fashion.

8.7.5 Scrub Nurse Procedure

8.7.5.1 When handed a syringe of marrow, attach the syringe to the collection bag Luer lock, un-clamp the stop cock to the collection bag and depress the TRAC valve. Then inject the marrow into the collection bag. Following this injection into the collection bag, make sure the collection bag clamp is closed, open up the anticoagulation bag clamp, depress the TRAC valve to that 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.

8.7.5.2 For each 500ml of marrow collected in the collection bag, inject 10ml of the heparin-Plama-lyte solution from the anticoagulation bag into the collection bag through the same port that is used to inject the marrow.

8.7.5.3 At the end of the procedure, transfer the heparin-Plama-lyte solution from the anticoagulation bag to the collection bag.

8.7.6 Based on pre-planned marrow volume, complete the harvest.

NOTE: 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.

8.7.7 Post harvest

8.7.7.1 Sterilely attach 850 micron, 500 micron and 200 micron triple filter set up to the bone marrow collection bag. Attach the appropriate transfer bag (2000ml or 600ml) to the bottom of the filter set.
8.7.7.2 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, obtain 10mls from the transfer bag and send to the STCL.

8.7.7.3 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.

8.7.7.4 Labeling the bone marrow product will occur before the cellular therapy product bag is removed from the proximity of the donor.

8.7.7.5 Label the transfer pack using the provided labels:

- 8.7.7.5.1 Patient identification label shall include at a minimum proper name of the product and the unique numeric or alphanumeric identifier.
- 8.7.7.5.2 On demand product label containing ISBT identification number.
- 8.7.7.5.3 Attach patient identification labels to bag containing bone marrow.

8.7.7.6 Dressing the operative sites
- 8.7.7.6.1 Clean operative site with warm sterile saline and dry thoroughly.
- 8.7.7.6.2 Apply sterile dressings and secure with a pressure dressing.

8.7.8 Transport of product to STCL

- 8.7.8.1 Place the marrow-filled transfer pack and research syringe(s) in the designated transport container (cooler) for transport to the STCL.

- 8.7.8.2 The following paperwork must accompany the product
  - 8.7.8.2.1 Donor Summary of Eligibility
  - 8.7.8.2.2 BMH Quality Assurance Form

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

8.7.9 Reverse anesthesia and transport the patient to Post-Anesthesia Care Unit.

9 RELATED DOCUMENTS/FORMS

9.1 FRM1 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

<table>
<thead>
<tr>
<th>Revision No.</th>
<th>Author</th>
<th>Description of Change(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>06</td>
<td>Jennifer Frith</td>
<td>Added 8.7.7.4</td>
</tr>
</tbody>
</table>
**Signature Manifest**

**Document Number:** ABMT-COLL-017

**Title:** Bone Marrow Harvest Procedure

All dates and times are in Eastern Time.

**ABMT-COLL-017 Bone Marrow Harvest Procedure**

**Author**

<table>
<thead>
<tr>
<th>Name/Signature</th>
<th>Title</th>
<th>Date</th>
<th>Meaning/Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jennifer Frith</td>
<td></td>
<td>09 Aug 2018, 04:01:04 PM</td>
<td>Approved</td>
</tr>
</tbody>
</table>

**Management**

<table>
<thead>
<tr>
<th>Name/Signature</th>
<th>Title</th>
<th>Date</th>
<th>Meaning/Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jennifer Frith</td>
<td></td>
<td>09 Aug 2018, 04:01:14 PM</td>
<td>Approved</td>
</tr>
</tbody>
</table>

**Medical Director**

<table>
<thead>
<tr>
<th>Name/Signature</th>
<th>Title</th>
<th>Date</th>
<th>Meaning/Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nelson Chao</td>
<td></td>
<td>11 Aug 2018, 03:04:06 AM</td>
<td>Approved</td>
</tr>
</tbody>
</table>

**Quality**

<table>
<thead>
<tr>
<th>Name/Signature</th>
<th>Title</th>
<th>Date</th>
<th>Meaning/Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bing Shen</td>
<td></td>
<td>12 Aug 2018, 12:59:33 AM</td>
<td>Approved</td>
</tr>
</tbody>
</table>

**Document Release**

<table>
<thead>
<tr>
<th>Name/Signature</th>
<th>Title</th>
<th>Date</th>
<th>Meaning/Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Betsy Jordan</td>
<td></td>
<td>13 Aug 2018, 07:55:52 AM</td>
<td>Approved</td>
</tr>
</tbody>
</table>