



## Division of Cellular Therapy

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Bone Marrow Harvest Procedure

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## ABMT-COLL-017

# BONE MARROW HARVEST PROCEDURE

### 1 PURPOSE

- 1.1 Bone marrow is harvested in operative suite(s) Bone marrow is used as a rescue following myeloablative or non-myeloablative therapy in the treatment of a variety of malignancies or other transplantable diseases; see APBMT-COMM-001 *Donor Selection, Evaluation and Management*.
- 1.2 For the adult and pediatric programs, bone marrow harvest are 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 A bone and marrow transplant attending physician, who is assisted by an advanced practice provider (APP), fellow, or second attending harvests bone marrow.
- 3.2 Anesthesia is administered under the direction of a licensed adult 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 DUMC      Duke University Medical Center
- 4.3 Kgs        Kilograms
- 4.4 Mat Mgmt. - Materials Management
- 4.5 ml         Milliliters
- 4.6 PPE        Personal Protective Equipment
- 4.7 QC         Quality Control
- 4.8 SOPs       Standard Operating Procedures
- 4.9 STCL       Stem Cell Laboratory

## 5 MATERIALS

- 5.1 Stem Cell Laboratory
- 5.2 Supply kit (pre-stocked)
- 5.3 Syringes, 5 ml Luer-tip DUMC Mat Mgmt. (B-D)
- 5.4 Syringes, 10 ml Luer-tip DUMC Mat Mgmt. (B-D)
- 5.5 Needle, 19 g, 1½" DUMC Mat Mgmt. (B-D)
- 5.6 Plasma-lyte A Injection - 500ml bags Baxter, Product # 2B2543
- 5.7 Validated transport container (cooler)

## 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 20ml DUMC Mat Mgmt. (B-D)
    - 6.2.7.2 Six 60ml 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 Beaker, 600ml, 50ml
  - 6.2.11 Scissors, 1 ea.
  - 6.2.12 One 3ml Luer tip syringe - DUMC Mat Mgmt. (B-D)
  - 6.2.13 Towels

- 6.2.14 Sponge, dressing
- 6.2.15 Gloves - DUMC Mat Mgmt.
- 6.2.16 Surgical packs
- 6.2.17 Breast/chest sheet
- 6.2.18 Custom Basic pack
- 6.2.19 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](http://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 aspirate and core biopsy
  - 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 Other laboratory studies
  - 8.1.5.1 Hematologic
    - 8.1.5.1.1 Complete blood count, including platelets
  - 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 Infectious Disease Markers
    - 8.1.5.3.1 Donor referral NTL panel
    - 8.1.5.3.2 VZV IgG AB
    - 8.1.5.3.3 HSV IgG AB
    - 8.1.5.3.4 Toxo IgG & IgM AB
    - 8.1.5.3.5 EBV AB
    - NOTE:** Additional markers may be performed according to CDC recommendations.
    - 8.1.5.3.6 Pregnancy test, serum beta-HCG, rapid (female patients of appropriate age) and testing must be completed within 7 days prior to anesthesia and colony stimulating factor administration.
  - 8.1.5.4 Tumor markers, if applicable
- 8.2 Patient- Autologous or Allogeneic Donor Preparation
  - 8.2.1 Immediate pre-operative screening
  - 8.2.2 Pre-operative screening includes an overall assessment of donor suitability immediately prior to the harvest procedure.
  - 8.2.3 Donor suitability will be documented in the EMR by the attending physician, then verified by the team performing the harvest collection prior to the collection procedure.
  - 8.2.4 Laboratory studies (at minimum)
    - 8.2.4.1 Complete blood counts, platelets
    - 8.2.4.2 Coagulation studies: PT, PTT
    - 8.2.4.3 Serum electrolytes
    - 8.2.4.4 Type and screen

- 8.2.4.5 Urinalysis, clean catch (adults only)
- 8.2.4.6 Infectious Disease Markers
  - 8.2.4.6.1 Donor referral NTL panel
  - 8.2.4.6.2 VZV IgG AB
  - 8.2.4.6.3 HSV IgG AB
  - 8.2.4.6.4 Toxo IgG & IgM AB
  - 8.2.4.6.5 EBV AB
  - 8.2.4.6.6 Pregnancy test, serum beta-HCG, rapid (female patients of appropriate age) and testing must be completed within 7 days prior to anesthesia and colony stimulating factor administration.
  - 8.2.4.6.7
    - NOTE:** Additional markers may be performed according to CDC recommendations.
- 8.2.4.7 Other pre-operative tests and preparations
  - 8.2.4.7.1 Chest x-ray
  - 8.2.4.7.2 EKG (for adults only)
  - 8.2.4.7.3 Anesthesia evaluation
  - 8.2.4.7.4 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 the procedures performed to protect the health of the donor and the recipients
    - 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 Blood loss
- 8.3.9 Decreased blood pressure
- 8.3.10 Hypovolemic shock
- 8.3.11 Death
- 8.3.12 Intent of the collection for research, if applicable
- 8.3.13 Protection of medical information and confidentiality
  - 8.3.13.1 For additional information regarding the consenting process, see related policy ABMT-GEN-024 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.

#### 8.5 Blood Product Availability

- 8.5.1 Ensure autologous or CMV-appropriate and irradiated blood components shall be available during the marrow collection procedure for all donors.
- 8.5.2 If required, ensure allogeneic blood products administered to the donor during the marrow collection procedure are to be irradiated prior to transfusion.
- 8.5.3 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.
- 8.5.4 Preparation of Plasma-lyte A solution:
  - 8.5.4.1 Add 10ml of 5,000 unit/ml preservative free heparin to 500ml of Plasma-lyte A Injection media in the Plasma-lyte A bag,
  - 8.5.4.2 Inject 100ml of the solution into the 600ml anticoagulation bag.
  - 8.5.4.3 Transfer 100ml of the solution into the 1,500ml collection bag.
  - 8.5.4.4 Flush all collection syringes with the heparin solution.

- 8.5.5 Harvest
  - 8.5.5.1 Induce anesthesia
  - 8.5.5.2 Call a time out.
  - 8.5.5.3 Select the site of aspiration.
    - 8.5.5.3.1 Posterior iliac bone
    - 8.5.5.3.2 Anterior iliac crests and/or sternum
- 8.5.6 Position patient
  - 8.5.6.1 Prepare operative field with prep regimen.
  - 8.5.6.2 Drape field with sterile towels and breast/chest sheet.
  - 8.5.6.3 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.
  - 8.5.6.4 Advance the needle into the bone, using a gentle but firm twisting motion.
  - 8.5.6.5 When the needle is firmly seated in the marrow cavity, remove the trocar from the needle.
  - 8.5.6.6 Attach a 20ml or 60ml 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.
  - 8.5.6.7 When the aspiration is completed, grasp the syringe and twist/remove from the needle.
  - 8.5.6.8 Hand the syringe to the scrub nurse.
  - 8.5.6.9 Place the trocar back and remove the needle from the bone or advance the needle to new marrow spaces and repeat as above
  - 8.5.6.10 Repeat the aspirate procedure, using the same skin incision site for multiple entries into the bone, in a clockwise fashion.
- 8.5.7 Scrub Nurse Procedure
  - 8.5.7.1 When handed a syringe of marrow, attach the syringe to the collection bag Luer lock, un-clamp the stopcock 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.

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

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

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

8.5.8 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).

8.5.9 Post-harvest

8.5.9.1 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.

8.5.9.2 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.

8.5.9.3 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.

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

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

- 8.6.1 This step will include donor identification verified against the label information, prior to removing the product from the proximity of the donor.
- 8.7 Label all samples using the provided labels. When possible, ensure a sufficient area of the container remains unobstructed to permit inspection of the contents.
- 8.8 On demand product label containing ISBT identification number.
  - 8.8.1 Attach patient identification labels to bag containing bone marrow.
  - 8.8.2 Verify labels are attached securely and processes were performed accurately
- 8.9 Dressing the operative sites
  - 8.9.1 Clean operative site with warm sterile saline and dry thoroughly.
  - 8.9.2 Apply sterile dressings and secure with a pressure dressing.
  - 8.9.3 Reverse anesthesia and transport the patient to Post-Anesthesia Care Unit.
  - 8.9.4 Transport of product to STCL
    - 8.9.4.1 Place the bone marrow-filled transfer pack and research syringe(s) in the designated transport container (cooler) for transport to the STCL.
    - 8.9.4.2 The following paperwork must accompany the product
    - 8.9.4.3 APBMT-COMM-001 FRM2 Summary of Donor Eligibility and Infectious Disease Testing
    - 8.9.4.4 STCL-SOP-050 Infusion Form
    - 8.9.4.5 STCL-FORM-037 Bone Marrow Harvest Quality Assurance Sheet
    - 8.9.4.6 STCL-FORM-056 Cellular Therapy Infusion Request Form (if applicable)
    - 8.9.4.7 STCL-FORM-062 Stem Cell Laboratory Processing Order Form (if applicable)
  - 8.9.5 Fill out Cellular Product Distribution Form for Cooler located on the outside of transport container.

Cellular Product Distribution Form for Cooler: (Check ONE)	
<input type="checkbox"/>	N5100, Duke North Hospital, Erwin Road, Durham, NC 27705 (5 <sup>th</sup> Floor) Contact Person: Charge Nurse Phone #: 919-681-5141
<input type="checkbox"/>	N5200, Duke North Hospital, Erwin Road, Durham, NC 27705 (5 <sup>th</sup> Floor) Contact Person: Charge Nurse Phone #: 919-681-5241
<input type="checkbox"/>	N9200, Duke North Hospital, Erwin Road, Durham, NC 27705 (9 <sup>th</sup> Floor) Contact Person: Charge Nurse Phone #: 919-681-9241
<input type="checkbox"/>	CHC, Children's Heath Center, Erwin Road, Durham, NC 27705 (4 <sup>th</sup> Floor) Contact Person: Charge Nurse Phone #: 919-668-4490
<input type="checkbox"/>	ABMT Clinic, 2400 Pratt Street, Suite 1100, Durham, NC 27705 Contact Person: Charge Nurse Phone #: 919-681-9241
<input type="checkbox"/>	Other Location's Address: _____ Contact Person's Name: _____ Phone #: _____

## 9 RELATED DOCUMENTS/FORMS

- 9.1 APBMT-COMM-001 Donor Selection, Evaluation, and Management
- 9.2 APBMT-COMM-001 FRM2 Summary of Donor Eligibility and Infectious Disease Testing
- 9.3 ABMT-GEN-054 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-056 Cellular Therapy Infusion Request Form
- 9.7 STCL-FORM-062 Stem Cell Laboratory Processing Order Form (if applicable)
- 9.8 DUHS policy: DUHS Standard & Transmission-based Precautions
- 9.9 DUHS Policy: DUHS Hand Hygiene
- 9.10 DUHS policy: DUHS Clinical Engineering Policy Inspection of Patient Related Equipment
- 9.11 DUH Policy: Operating Room Cleanliness

## 10 REFERENCES

- 10.1 Internal Procedure for Duke University Medical Center Autologous Blood and Marrow Transplant Program.

## 11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
07	Jennifer Frith	<ul style="list-style-type: none"> <li>Section 6.1 – updated to reflect hospital policy for equipment.</li> </ul>

Revision No.	Author	Description of Change(s)
		<ul style="list-style-type: none"> <li>• Section 6.2 – List of equipment updated to reflect current utilization. Item numbers added where applicable for ease of locating</li> <li>• Section 7.1 – related safety policies inserted</li> <li>• Section 8.3 – updated to reflect alignment with current FACT standards for testing and procedures, collection for research, protection of medical information, confidentiality.</li> <li>• Section 8.2.4.6 – added pregnancy test requirements</li> <li>• Section 8.3 – Reference to related policy for consenting</li> <li>• Section 8.5.1. – updated to reflect CMV requirements in alignment with FACT standards</li> <li>• Section 8.5.3– updated to include: 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.</li> <li>• Section 8.6.1 – labeling requirements updated to include donor verifications steps.</li> <li>• Section 8.9.4.3 added associated form</li> <li>• Section 8.9.4.4- added associated form</li> <li>• Section 8.9.4.5- added associated form</li> <li>• Section 8.9.4.6-added associated form</li> <li>• Section 9 - updated to include a comprehensive list of related documents</li> </ul>

## Signature Manifest

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

#### Author

Name/Signature	Title	Date	Meaning/Reason
Jennifer Frith (JLF29)		01 Sep 2021, 09:24:56 AM	Approved

#### Management

Name/Signature	Title	Date	Meaning/Reason
Jennifer Frith (JLF29)		01 Sep 2021, 09:25:09 AM	Approved

#### Medical Director

Name/Signature	Title	Date	Meaning/Reason
Nelson Chao (CHAO0002)		01 Sep 2021, 09:48:43 AM	Approved

#### Quality

Name/Signature	Title	Date	Meaning/Reason
Bing Shen (BS76)		03 Sep 2021, 10:10:39 AM	Approved

#### Document Release

Name/Signature	Title	Date	Meaning/Reason
Betsy Jordan (BJ42)		03 Sep 2021, 01:20:07 PM	Approved