**Document Information**

<table>
<thead>
<tr>
<th>Revision: 09</th>
<th>Vault: ABMT-Collections-rel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Status: Release</td>
<td>Document Type: Collections</td>
</tr>
</tbody>
</table>

**Date Information**

| Creation Date: 05 Jun 2019 | Release Date: 19 Jul 2019 |
| Effective Date: 19 Jul 2019 | Expiration Date: |

**Control Information**

| Author: MC363 | Owner: MC363 |
| Previous Number: ABMT-COLL-015 Rev 08 | Change Number: APBMT-CCR-157, APBMT- |

CONFIDENTIAL - Printed by: ACM93 on 19 Jul 2019 08:18:07 am
ABMT-COLL-015
WHOLE BLOOD COLLECTION

1 PURPOSE
1.1 To describe the procedure for collection of whole blood.

2 INTRODUCTION
2.1 Donor lymphocytes can be harvested from an allogeneic donor unit of whole blood. Blood collection will be done by aseptic methods. If more than one venipuncture is needed, a new container and donor set will be used. The amount of blood collected, including samples should not exceed 10.5 mL per kilogram of patient weight (approximately 12% of total blood volume). For donors weighing less than 50 kg, calculations will be made for the volume of blood to be drawn and the volume of anticoagulant to remove from the blood bag. The whole blood collection procedure will meet FACT (Foundation for the Accreditation of Cellular Therapies), FDA (Food and Drug Administration) and AABB (American Association of Blood Banks) standards.

2.2 If a small volume of blood (20-60 mL) is ordered to be collected, a syringe method may be used. Whole blood will be withdrawn into an anticoagulated syringe which will be sent to the Duke Cryopreservation lab for processing.

2.3 For information regarding the identifications and treatment of possible side effects of whole blood donation refer to APBMT-COMM-035 Detection & Management of Adverse Events.

3 SCOPE AND RESPONSIBILITIES
3.1 The ABMT apheresis nurse and physician or physician extender will be responsible for the procedure. The physician will order the amount of whole blood to be removed and the anticoagulant type and volume.

4 DEFINITIONS/ACRONYMS
4.1 FACT: Foundation for the Accreditation of Cellular Therapies
4.2 FDA: Food and Drug Administration
4.3 AABB: American Association of Blood Banks
4.4 Kg: Kilogram
4.5 ABMT: Adult Blood and Marrow Transplant
4.6 DUMC: Duke University Medical Center
4.7 ISBT: International Society for Blood Transfusion
4.8 IV: Intravenous
4.9 mL: milliliter
5 MATERIALS

5.1 600 mL Transfer pack
5.2 Sampling site coupler
5.3 IV Start kit
5.4 Seal Safe System from Terumo
5.5 Hemostat
5.6 Squeeze ball
5.7 20, 30 or 60 mL syringes for Syringe Method
5.8 20 gauge needle
5.9 Tubing Stripper
5.10 18 or 20 gauge angiocath IV
5.11 IV extension set
5.12 Forms and labels
  5.12.1 Procedure consent
  5.12.2 STCL-FORM-041 Doctor’s Orders Adult Stem Cell Transplant Program
  5.12.3 APBMT-COMM-002 Adult Donor Health History Questionnaire
  5.12.4 APBMT-COMM-007 Important Information You Must Know About Stem Cell or Other Cellular Therapy Donations to Stem Cell Transplant Patients
  5.12.5 STCL-GEN-009 FRM1 Cellular Product Chain of Custody
  5.12.6 APBMT-COMM-001 FRM3 Summary of Donor Eligibility and Infectious Disease Testing (ABMT)
  5.12.7 Whole Blood Base Label
  5.12.8 Unique identifier (ISBT-128) bar code label
  5.12.9 Tie tag containing donor and recipient identification

6 EQUIPMENT

6.1 Scale
6.2 Seal Safe System from Terumo BCT

7 SAFETY

7.1 Follow all safety-related standard operating procedures and wear all necessary personal protective equipment when handling potentially hazardous blood and body fluids to include, but not limited to gloves, gowns, surgical masks, goggles, and/or face shields.
8 PROCEDURE

8.1 Identify donor and place identification band on donor wrist.

8.2 Confirm signed order for whole blood collection on STCL-FORM-041 Doctor’s Orders Adult Stem Cell Transplant Programs.

8.3 Assess donor, explain the procedure, take vital signs and weight, and draw up ordered dose of heparin.

8.3.1 For donors weighing less than 50 kg refer to Table 1.

Table 1.

Calculation for Drawing Donors Weighing Less than 50 kg

Volume to draw = (Donor’s weight in kg/50) x 450 ml

Amount of anticoagulant needed = (A/100) x 14

Amount of anticoagulant to remove from collection bag = 63 ml - B

8.4 Complete the Adult Donor History Questionnaire and ask donor to read APBMT-COMM-007 Important Information You Should Know about Stem Cell or Other Cellular Therapy Donations to Stem Cell Transplant Patients. Refer to APBMT-COMM-002 Adult Donor Health History Questionnaire. Obtain donor consent.

8.5 Perform Quality Control of the scale if not completed for the day. Refer to Quality Control of Scale.

8.6 Inspect transfer pack.

8.6.1 Insert a sampling site coupler into a port of the transfer pack and aseptically inject the anticoagulant.

8.7 Attach Base label, bar codes and demographic tie tag labels to the bag. Refer to COMM-PAS-003 Labeling Cellular Therapy Products.

8.8 Place blood bag on the scale and turn the dial indicator to zero.

8.9 Place donor in bed or in a reclining chair with feet up.

8.10 Apply tourniquet and select a large vein for venipuncture.

8.11 Scrub a 3 inch diameter area around the venipuncture site for 30 seconds with chlorohexadine.

8.12 Do not re-palpate the area once the site has been prepared.

8.13 Cover the prepared site with sterile gauze if venipuncture will not be done immediately.

8.14 Perform venipuncture. Refer to ABMT-COLL-011 Venipuncture Procedure.

8.15 Secure the needle with tape and instruct the donor to squeeze the ball.

8.16 Gently rock the blood bag to mix the anticoagulant with the blood.

8.17 Closely monitor the weight of the bag and clamp the tubing with a hemostat when the desired bag weight has been reached (450 mL +/- 45 mL for blood tests) for donors weighing more than 50 kg.
8.18 Remove the angiocath IV and apply pressure and a pressure bandage to the venipuncture site.

8.19 Strip the blood in the tubing into the bag and heat seal the tubing a minimum of two times using seal safe system from Terumo BCT.

8.20 Pull the tubing at one of the heat seal sites and discard the needle in the biohazard container.

8.21 Take vital signs and give donor a drink and snack.

8.22 Have donor rest for at least 15 minutes following donation.

8.23 Double check all donor and patient names and identification numbers.

8.24 Record date and time on the whole blood base label and transport the blood bag to the lab in the cooler. Refer to STCL-GEN-009 Packaging and Transporting Non-Frozen Cellular Products Locally.

8.25 Enter a nursing note in Electronic medical record.

8.26 Syringe Method

8.26.1 Identify donor and place identification band on donor wrist.

8.26.2 Assess donor, explain the procedure, take vital signs, and weight.

8.26.3 Obtain an order from the physician for the amount of whole blood to be removed by syringe and the amount of Heparin (1000 units/mL) to be added to the syringe.

8.26.4 Complete the Adult Donor Health History Questionnaire and ask donor to read APBMT-COMM-007 Important Information You Should Know about Stem Cell or Other Cellular Therapy Donations to Stem Cell Transplant Patients. Refer to APBMT-COMM-002 Adult Donor Health History Questionnaire. Obtain donor consent.

8.26.5 Perform Quality Control of the scale if not completed for the day. Refer to Quality Control of Scale.

8.26.6 Draw up the heparin into the syringes to be used for whole blood collection.

8.26.7 Attach Base label, bar codes and demographic tie tag labels to the bag. Refer to COMM-PAS-003 Labeling Cellular Therapy Products.

8.26.8 Place blood bag on the scale and turn the dial indicator to zero.

8.26.9 Prepare the venipuncture site as described above.


8.26.11 Secure the needle with tape and instruct the donor to squeeze the ball.

8.26.12 Slowly pull the plunger to prevent collapsing the vein.

8.26.13 Gently rock the syringe to mix the anticoagulant with the blood.

8.26.14 When collection is complete, cap the syringe with a sterile needle.
8.26.15 Remove the angiocath IV and apply pressure and a pressure bandage to the venipuncture site.

8.26.16 Take vital signs and have donor rest for at least 5 minutes following donation.

8.26.17 Double check all donor and patient names and identification numbers

8.26.18 Record date and time on the whole blood base label and transport the blood bag to the lab in the cooler. Refer to STCL-GEN-009 Packaging and Transporting Non-Frozen Cellular Products Locally.

8.26.19 Enter a nursing note in the Electronic medical record and give the donor Post donation instructions.

9 RELATED DOCUMENTS/FORMS

9.1 ABMT-COLL-011 Venipuncture Procedure
9.2 APBMT-COMM-001 FRM3 Summary of Donor Eligibility and Infectious Disease Testing (ABMT)
9.3 APBMT-COMM-002 Adult Donor Health History Questionnaire
9.4 APBMT-COMM-007 Important Information You Should Know About Stem Cell or Other Cellular Therapy Donations to Stem Cell Transplant Patients
9.5 APBMT-COMM-035 Detection & Management of Adverse Events
9.6 COMM-PAS-003 Labeling Cellular Therapy Products
9.7 STCL-GEN-009 FRM1 Cellular Product Chain of Custody Form
9.8 STCL-FORM-041 Doctor's Orders Adult Stem Cell Transplant Programs.
9.9 STCL-GEN-009 Packaging and Transporting Non-Frozen Cellular Products Locally

10 REFERENCES


11 REVISION HISTORY

<table>
<thead>
<tr>
<th>Revision No.</th>
<th>Author</th>
<th>Description of Change(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>09</td>
<td>Mary Beth Christen</td>
<td>References to APBMT-COMM-035 updated with current title.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Inserted new title: APBMT-COMM-001 FRM3.</td>
</tr>
</tbody>
</table>
# Signature Manifest

Document Number: ABMT-COLL-015
Title: Whole Blood Collection

All dates and times are in Eastern Time.

## ABMT-COLL-015 Whole Blood Collection

### Author

<table>
<thead>
<tr>
<th>Name/Signature</th>
<th>Title</th>
<th>Date</th>
<th>Meaning/Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sally McCollum (MOORE171)</td>
<td></td>
<td>02 Jul 2019, 03:35:07 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 (JLF29)</td>
<td></td>
<td>08 Jul 2019, 03:11:03 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 (CHAO0002)</td>
<td></td>
<td>08 Jul 2019, 03:37:10 PM</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>(RB232 ) for Bing Shen (BS76)</td>
<td></td>
<td>09 Jul 2019, 07:38:48 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 (BJ42)</td>
<td></td>
<td>09 Jul 2019, 01:19:21 PM</td>
<td>Approved</td>
</tr>
</tbody>
</table>