Carter BloodCare

To: Transfusion Services Managers
From: Hospital Relations
Date: January 20, 2020
Re: Customer Service Manual updates

Please update the Customer Service Manual by removing and replacing the following pages or forms.

Section 1.0 General Information
Effective immediately, the organizational charts are revised to accommodate name changes.

Section 4.0 Transfusion Complications
Effective, 1/24/2020, the following form has been revised to move instructions to the top and add °F for pre and post-transfusion temperatures.

RTF215.01A Transfusion Reaction Investigation

Section 8.0 Special Donations
Page 8-10 is revised to clarify contact information for scheduling therapeutic appointments and forms listed below contain minor revisions. Revisions are effective 1/28/2020.

SDF801.01 Autologous Blood Donation Request
SDF801.02 Request for Directed Donor
SDF801.03 Therapeutic Donor Request

Section 9.0 Distribution
The following forms have been revised for ease of use and the investigation form updated to clarify return options; both effective 1/21/2020.

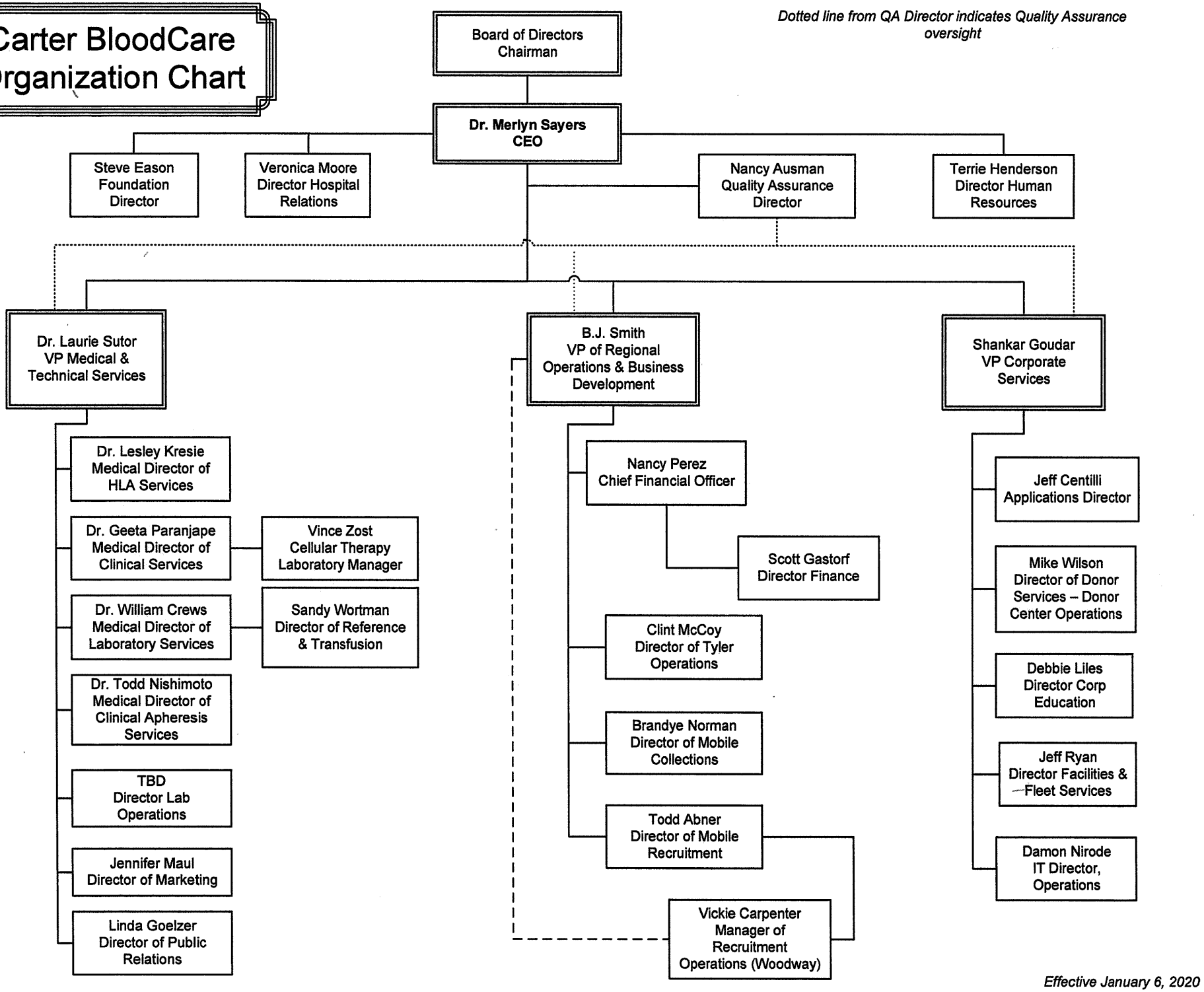
DPF300.03 Hospital Report of Returned Blood Components to Carter BloodCare
DPF300.03A Return of Blood for Investigation

Section 12.0 Reference and Transfusion
The unit antigen tag has been revised to remove 'Research Use Only' as the testing platform is FDA licensed; effective 1/20/2020.

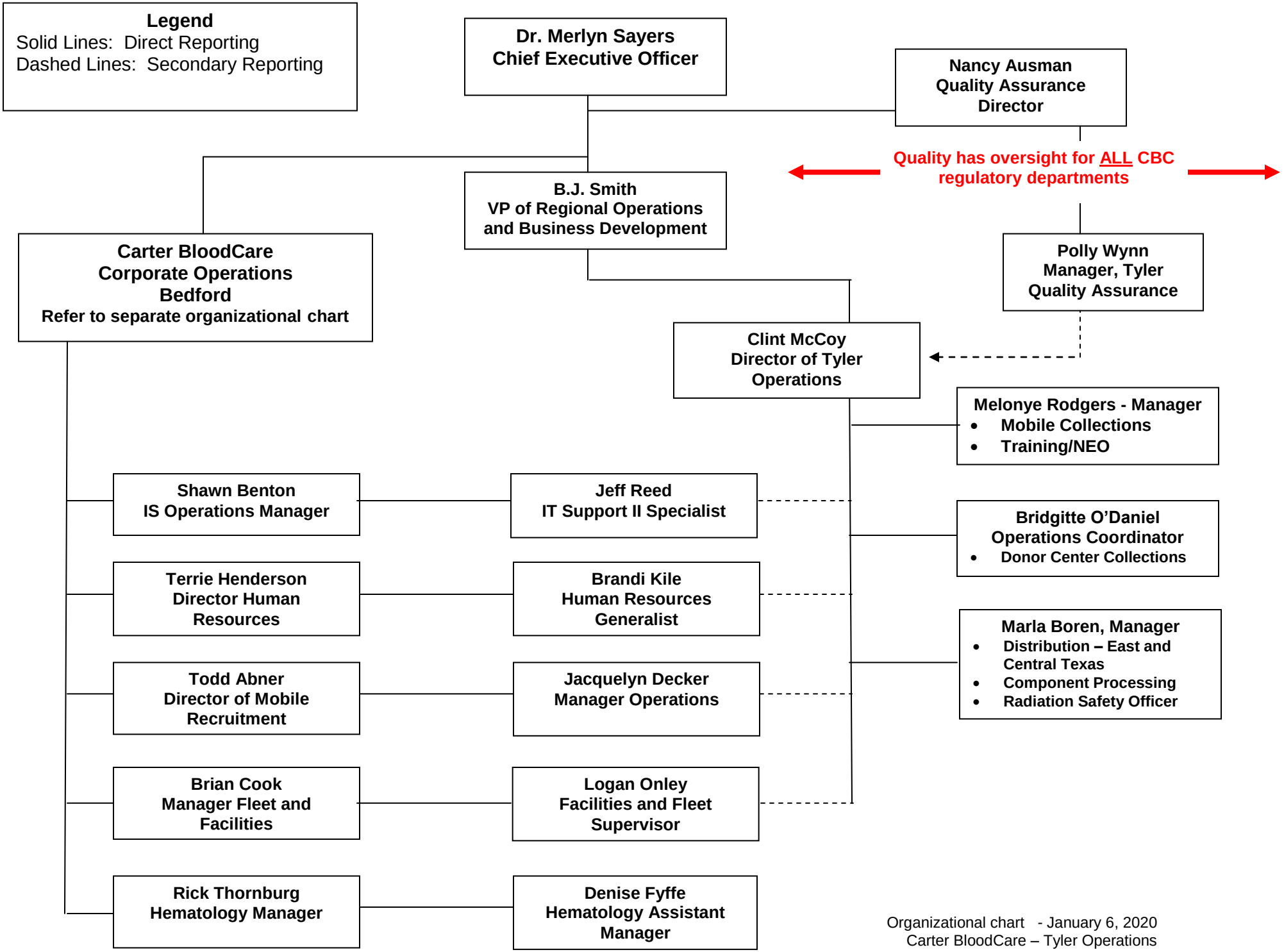
RTL207.01C Molecular Matched Antigen Typing

Carter BloodCare Organization Chart

Dotted line from QA Director indicates Quality Assurance oversight



Effective January 6, 2020



Organizational chart - January 6, 2020
Carter BloodCare – Tyler Operations

neighborhood donor centers. Appointments are scheduled Monday through Friday. Walk-ins will not be accepted.

8.4.4 Associated Fee

A fee is charged for all donors at the time of the procedure. Carter BloodCare will accept a money order, cashier's check or travelers check, or, if arranged in advance, a credit card as form of payment. A convenience fee applies for the credit card. Cash will not be accepted.

8.4.5 Unit Disposition

Units collected from a therapeutic phlebotomy procedure are not acceptable for release into general inventory. Units are not tested and are discarded after withdrawal.

8.5 Hereditary Hemochromatosis (HH) and Low Testosterone (LOT) Programs

8.5.1 Enrollment for No-Fee Phlebotomy

Patients diagnosed with hereditary hemochromatosis (HH) or receiving testosterone therapy (LOT) and requiring therapeutic phlebotomy as part of their treatment may qualify to have their units used for transfusion through special programs. These programs require a physician's prescription (refer to form DNF104.35C) and enrollment in the appropriate program. Please contact the Donor Notification department for additional information on these programs at 817-412-5603.

HH and LOT donors who do not meet established criteria as regular volunteer donors will be deferred from allogeneic blood donations, but may still receive phlebotomy if enrolled in the HH or LOT programs. Patients with a diagnosis other than HH or erythrocytosis due to testosterone therapy may not be drawn through these programs and may only be drawn as therapeutic donors.

8.5.2 HH and Lot Program Scheduling

Once the DNF104.35C, Enrollment/Prescription for No-Fee Phlebotomy Form or other required forms for HH have been approved by the Donor Notification department, the donor/patient will receive written notification.

HH and LOT donations/phlebotomies are scheduled through Carter BloodCare's Contact Center at 817-412-5830. These must be scheduled in advance as walk-ins are not accepted.

8.6 Special Donations Example Forms

Carter BloodCare

TRANSFUSION REACTION INVESTIGATION

NOTE: All fields must be completed or a delay in transfusion reaction investigation may occur.

Infusionist Instructions:

1. Immediately discontinue transfusion. Keep IV line open with normal saline (0.9% sodium chloride) or other FDA approved blood administration solution.
2. Check all forms, labels, and patient identification.
3. Notify attending physician and Carter BloodCare Reference and Transfusion Services.
4. Properly collect and label post-transfusion purple top (EDTA) anticoagulated specimen. Minimum 3 mL sample required.
5. Document all required information in the "Patient Information" section (you may apply a patient sticker).
6. Document all required information in the "Infusionist Report" section.
7. Send samples, blood component container with attached administration set and intravenous solutions, compatibility tag, and this completed form to Carter BloodCare Reference and Transfusion Services STAT.

Patient Information

Patient Name: _____ Facility Name: _____

Identification Number: _____ Ordering Physician: _____

Diagnosis: _____

_____

Infusionist Report

Unit Number(s): _____

Component(s) Involved: _____ Amount(s) Transfused: _____

All forms, labels and patient identification have been verified. ☐ Yes ☐ No

Date/Time Transfusion Started: _____ Date/Time of Reaction: _____

Date/Time Transfusion Stopped: _____ Infusionist: _____

Person Completing Form: _____ Date/Time: _____

Pre-Transfusion	Post-Transfusion	Patient Symptoms
Temperature: _____ °F	Temperature: _____ °F	☐ Chills ☐ Nausea
Pulse: _____	Pulse: _____	☐ Fever ☐ Urticaria
Blood Pressure: _____	Blood Pressure: _____	☐ Dyspnea ☐ Hematuria
		☐ Shock ☐ Back or Chest Pain
		☐ Jaundice ☐ Other_____
		_____

Carter BloodCare
2205 Highway 121
Bedford Texas 76021
(p) 817-412-5740
(f) 817-412-5749
CLIA# 45D0486046

Carter BloodCare

AUTOLOGOUS BLOOD DONATION REQUEST

Physician's office:
Please fax this form at least
10 days before date of surgery to:
817-412-5318

Full Legal Name: _____ SSN: _____
Last First Middle

Patient's Address: _____
Street City Zip Code

Birth Date: _____ Sex: _____ Phone: _____ _____
MM/DD/YY Home Business (& Ext.) Cell

Patient Scheduled for: _____ at _____ on _____
Surgical Procedure Complete Hospital Name Date

Components Needed: [_____] Red Blood Cell RBC [_____] Fresh Frozen Plasma FFP [_____] Cryoprecipitate CRYO
Quantity Quantity Quantity

Pre-Assessment Questions	NO	YES	If "YES," explain
1. Is the patient currently taking an antibiotic or any other medication for an infection?	☐	☐	
2. Has the patient EVER had any type of cancer, including leukemia?	☐	☐	
3. Has the patient EVER had any problems with their heart or lungs?	☐	☐	
4. Has the patient had a bleeding condition or a blood disease?	☐	☐	
5. In the past 6 weeks, has the patient been pregnant or is the patient pregnant now?	☐	☐	

Physician Statement:

I have explained the advantages and disadvantages of autologous blood transfusions to my patient. I realize an autologous donation is not always possible. I also understand that autologous donation may cause my patient to be anemic in the period leading up to the surgery. I understand the blood unit(s) that my patient donates may be unavailable for use due to circumstances beyond CARTER BLOODCARE's control.

I also understand that occasionally, an adverse reaction may occur during or after my patient's donation. Such adverse reactions include, but are not limited to, bruising, accidental arterial puncture, bleeding after leaving the donation site, infection, temporary loss of bladder control, seizure, blood clot formation (thrombosis), vein inflammation (phlebitis), nerve injury and/or a fainting spell which may include dizziness, nausea and vomiting.

I also understand my patient will be assessed a fee for the autologous donation(s).

Physician's Name (Print) _____ Physician's Signature _____ Date _____

Address: No. Street Suite # _____ City State Zip _____

Telephone Number _____ Fax Number _____

CALL 817-412-5308 FOR APPOINTMENTS

For CBC Use Only

Section B: (*Completed by Carter BloodCare Medical Director)*

☐ Approved for autologous donation ☐ Prepaid: _____
Amount and Payment Type, i.e., Money Order (MO) ,Credit Card (CC), or NMDP

☐ Approved pending clearance from cardiologist or primary care physician ☐ Waive Fee: _____ _____
Manager/MD Approval Date

☐ Not approved for donation ☐ MD approval NOT required

_____ _____
Employee Initials/Employee # Date

Comments:

Carter BloodCare Medical Director Signature: _____ Date: _____

Carter BloodCare

REQUEST FOR DIRECTED DONOR

Physician's office:
Please fax this form at least
10 days before date of surgery to:
817-412-5318

THIS SECTION TO BE COMPLETED BY PHYSICIAN (PRINT CLEARLY or TYPE)

Patient Name: _____ MRN: _____
Last First

Patient's Address: _____
Street City Zip Code

SSN: _____ Hospital: _____
(Required for hospital verification/tag on unit)

Patient Blood Type: _____ Date of Birth: _____ Sex: _____
MMDDYY

Blood Components Needed [_____] Red Blood Cell RBC [_____] Cryoprecipitate CRYO [_____] Fresh Frozen Plasma FFP
Quantity Quantity Quantity

[_____] Apheresis Platelets [_____] Pediatric Red Cells (No. of Donors)
Quantity Quantity

CALL 817-412-5308 FOR APPOINTMENTS
NO EMERGENCY DIRECTED DONATIONS

1. Patient or the family must arrange for sufficient donors to ensure the patient has enough acceptable units of blood. I also understand a fee will be assessed for the directed donation(s). I also understand the patient's and donor's blood types must be determined and documented on the forms before any donation appointments can be scheduled.
2. Women of child-bearing age should not receive blood donated by: their children, their husbands or their husband's blood relatives. This could result in development of antibodies which could cause problems in future pregnancies. In addition, although it is unlikely that most patients will face future organ transplant therapy, prior transfusion from immediate family members could prevent their use as organ donors.
3. Patients should not receive blood donated by blood relatives: mother, father, sister, brother or child, unless the blood component is irradiated to prevent GRAFT VERSUS HOST DISEASE (GVHD).
4. Donors must meet standards established by Food and Drug Administration, AABB and Carter BloodCare.
5. All directed donations for all components except apheresis platelets must be made no less than 5 days or more than 14 days prior to intended use.
6. Directed donations for platelets may be donated ONLY by apheresis from donors not on platelet inhibiting medicine. Platelets MUST be ordered 72 hours in advance of need.
7. If the directed donor units are not used by the patient, release of these units to the general inventory will be at the discretion of the hospital transfusion service.
8. Directed donor blood units may be rendered unsuitable for transfusion due to circumstances beyond Carter BloodCare's control. Therefore, Carter BloodCare cannot guarantee all units collected will be available for transfusion.
9. Although Carter BloodCare has careful donor selection procedures and extensive laboratory tests, there can be no guarantee that the directed donor blood is safe for transfusion and free of infections.

NOTE: Provide information of family member or designee who will donate for the patient or coordinate donations.

Contact Name: _____

Contact Phone #: _____

Requesting Physician: _____ _____/_____
(Please Print) Signature Date

Address: _____

Phone #: _____ Fax #: _____

The blood components will be used: _____
(Intended Date of Use)

For CBC Use Only
☐ Prepaid: _____ (Amount and payment type, i.e., money order [MO] or credit card [CC]).
Date Received by Carter BloodCare: _____ By: _____ Employee Initials/Employee #

Carter BloodCare

THERAPEUTIC DONOR REQUEST
(Fee will be Assessed)

Section A: Please complete patient/donor information.

Full Name: _____ Sex: _____ DOB: _____
Last First

Address: _____ Phone #: (_____)_____
Street City State Zip Code Area Code

Section B: Patients are encouraged to call 2 days prior to needing an appointment.

For appointments, contact Special Donations:
Phone: 817-412-5308
Fax: 817-412-5318

Diagnosis:

☐ Polycythemia Vera ☐ Polycythemia of unknown origin.

*For donors on testosterone or with hereditary hemochromatosis, contact the Donor Notification Department at 817-412-5603.

☐ Other: _____

Draw 1 unit of whole blood (approximately 500 mL)

☐ One time only ☐ Every 4 weeks ☐ Every 2 months ☐ Every 3 months

Target Hgb/Hct: ☐ 13% Hgb (39% Hct) ☐ 15% Hgb (45% Hct) ☐ Other: _____

(If boxes are left blank, the patient will be drawn at an Hgb of 13% or above or an Hct of 39% or above.)

Pre-Assessment Questions

1. Has the patient EVER had any problems with his/her heart or lungs? ☐ No ☐ Yes (describe), _____
2. For female patients, in the past 6 weeks has the patient been pregnant or is the patient pregnant now? ☐ No ☐ Yes (describe), _____

Physician's Name: _____

Physician's Signature: _____ Date: _____

Phone #: (_____)_____ Fax #: (_____)_____
Area Code Area Code

For CBC Use Only

Section C:

☐ Physician's cardiac clearance release sent to physician/donor _____ _____
Date Emp Initials/#

_____ _____ _____
Condition (if applicable) Emp. Initials/# Date

☐ Donor has had heart and/or lung change(s) within the past year

Comments:

(*Completed by Carter BloodCare Medical Director)*

☐ Approved for 1 time only ☐ MD approval NOT required

☐ Approved for therapeutic donation _____ _____
Employee Initials/# Date

☐ Approved pending clearance from cardiologist or primary care physician

☐ Not approved for donation

Comments:

_____ _____
Employee Initials/# Date

Carter BloodCare Medical Director Signature: _____ Date: _____

Carter BloodCare

HOSPITAL REPORT OF RETURNED BLOOD COMPONENTS TO CARTER BLOODCARE

FACILITY: _____
certifies that, while in possession of the following blood components, proper storage conditions were maintained at:

(Mark One): ☐ 1 – 6°C ☐ 20 – 24°C ☐ -18°C or colder

in accordance with AABB and FDA standards. The units have been inspected on the date of return and are free of visible hemolysis, clots, defects or abnormal appearance and have not been irradiated, manipulated, relabeled or modified by this institution in any way.

Component Type (Mark One): ☐ RBC/WB ☐ Platelet Products ☐ FFP/CPPLS ☐ CRYO/CRYO-POOL

☐ SEE ATTACHED PRINTOUT for unit information. Quantity: _____

☐ Unit(s) NOT Returned, Credit Request Only. *Document Product Code in Comment column below.

☐ MARK HERE if all units listed below are collected by Carter BloodCare and have the prefix number W0352

	Unit #	ABO/Rh	Expiration Date	Comment/*Product Code
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				

Hospital Tech: _____ Date: _____

Carter BloodCare HSR: _____ Date: _____

☐ MARK HERE if transported by courier service.

Carter BloodCare Supervisor:

Temperature: _____°C Packed OK? Y / N Signature: _____

KEY: RBC = red blood cell WB = whole blood FFP = fresh frozen plasma CPPLS = cryo-reduced plasma

Carter BloodCare

RETURN OF BLOOD FOR INVESTIGATION

Distribution Department – North, Central & East Texas

Facility Name: Contact Name:

Returned to (check one): ☐ Bedford (North Texas) ☐ Tyler (East Texas) ☐ Woodway (Central Texas)

RETURN REASON (check one): ☐ CBC Recall/Requested Return ☐ Other (be specific): _____

☐ Hemolysis or Clot ☐ Damaged Seal ☐ Appearance/Discoloration ☐ No Segments ☐ Labeling Issue ☐ ABO Discrepancy

PRODUCT TYPE (check one): ☐ RBC/WB ☐ PLATELET PRODUCT ☐ CRYO/CRYO POOL ☐ PLASMA ☐ OTHER (specify):

Unit #	Product Code	Expiration Date	Blood Type

This facility certifies that, while in its possession, the above listed components were maintained compliant with proper storage, handling and temperature requirements, in accordance with FDA regulations and AABB standards (except as noted in "RETURN REASON – Other").

Signature: _____ Date: _____

For Carter BloodCare Use Only

☐ Check here if returned by courier service & packed properly.

Temperature of Shipment: _____°C.

Employee Initials: _____ Employee #: _____

Carter BloodCare Distribution Supervisor/Designee

☐ Check here if unit is reflected on QSF508.05 Component Quarantine/Discard Request. No EDR Required.

☐ Check here if LifeTrak return is performed by an HSR and reviewed by supervisor/designee.

EDR#: _____ (or check here if N/A ☐)

Returning HSR: Employee #: _____

Date: / /

Name and ID of supervisor returning unit(s) in LifeTrak or reviewing return of unit(s) by CBC HSR

Date:

Carter Blood Care Laboratory Staff (Receipt of Products from Distribution)

Name and Employee #: Date: Time:

Comments:

RETURN OF BLOOD FOR INVESTIGATION
DIRECTIONS FOR COMPLETING THIS FORM

Hospital/Transfusion Service

NOTE: Press firmly and document clearly to ensure information is legible on all copies of the multiple page form.

1. Document the name of the facility returning blood for investigation. Do NOT use acronyms or initials.
2. Document employee contact name for the facility returning blood for investigation.
3. Mark the Carter BloodCare Distribution location this return is to be sent.
4. Mark the applicable "Return Reason." Be as specific as possible if selecting "Other."
5. Mark the applicable product type. Do NOT return more than 1 product type on a single form.
6. Enter applicable unit information in the spaces provided.
   NOTE: Check-digit is not required with the unit number.
7. Document signature and date, and retain the bottom (pink) copy for the facility's records. The yellow and white top-copies remain with the units.

For Carter BloodCare Use Only

Returned by Courier Service

1. Upon receipt, verify units were packed properly. Mark "Check here if returned by courier service and packed properly" box.
2. Document the temperature of the shipment.
3. Document employee initials and number.

Returned by Carter Bloodcare HSR

1. Verify all unit information documented on form corresponds with physical units being returned. Have the facility correct any errors.
2. Verify 1 "Reason for Return" and 1 "Product Type" are marked.
3. Verify the facility representative has signed and dated the form.
4. Document signature or initials in the "Returning HSR" space, and include the date of return and employee ID number. Leave the bottom (pink) copy with the facility.

Carter BloodCare Distribution Supervisor/Designee

1. If the unit is documented on QSF508.05 Component Quarantine/Discard Request, mark appropriate box.
   NOTE: An EDR is not required.
2. If Lifetrak return is performed by HSR, mark appropriate box.
3. Review form for accuracy and completeness prior to entering or immediately following return into LifeTrak. Document signature in "Review" space and document name and ID#.
4. Use the return code "RECAL" to complete the return in LifeTrak. Review and document initials on the pink copy of the return printout if the return is completed by an HSR.
5. Forward unit(s) to appropriate laboratory staff.
6. Attach yellow copy of the form to return printout.

Carter BloodCare Laboratory Staff

1. Document signature and employee ID number for receipt of unit(s) in the space provided.
2. Document discarded units or any additional information in the "Comments" section. Deliver the completed form to the Distribution Department.

Molecular Matched Antigen Typing

DIN: _____

Donor has been antigen tested using a Molecular Genotyping Assay and predicted negative for the following:

_____ Neg. _____ Neg.

_____ Neg. _____ Neg.

_____ Neg. _____ Neg.

_____ Neg. _____ Neg.

_____

_____

RTL207.01C
Version: 02

Carter BloodCare Effective Date: 01/20/2020