6.0 Special Donations

Contact Information:

Special Donations Department

Phone: (817) 412-5308

1(866) 525-3378

Fax: (817) 412-5318

6.1 Autologous Donations

6.1.1 Autologous Blood Donation Request

Form SDF801.01, Autologous Blood Donation Request, must be completed and signed by the physician. The Autologous Blood Donation Request form requests specific information about the patient, surgery date, surgical procedure, hospital, number and type of components requested, physician's information, pre-assessment questions, physician statement and financial responsibility.

Autologous donations will be limited to **whole blood units only** (no automated procedures). If more than one unit is requested, please ensure the patient has an adequate amount of time before surgery to donate the needed number of units.

For all North Texas, East Texas, and Central Texas donations, please fax the
completed form to the Special Donations department <u>at least 10 business days</u>
before anticipated date of surgery for medical review. Donors will **NOT** be
scheduled or permitted to donate unless the request has been received and
approved.

Request forms are available from the Special Donations and the Hospital Relations departments.

6.1.2 Autologous Donation Criteria

It is not necessary for autologous donation candidates to meet all usual blood donor criteria such as weight and hemoglobin. Because of the less strict donation criteria and abbreviated donor screening process, autologous components are restricted for the donor's use only and are not to be crossed-over into regular stock inventory. Because the autologous donor may not be in optimal health at the time of collection, a signed consent form from the patient's regular physician may be required. The consent must originate from the patient's primary care physician (PCP) or physician that treats the patient's disorder or concern. Conditions requiring consent include; history of cardiovascular problems, current pregnancy or any significant bleeding problems. The consent must be faxed to Special Donations along with the

<u>Autologous Blood Donation Request at least 10 business days before anticipated date</u> of surgery.

6.1.3 Autologous Donation Scheduling

Once the Autologous Donation Request Form has been approved, the Special Donations department will contact the patient to schedule the appointment(s). Autologous donations may be scheduled at least three days apart. Donations should be scheduled no more than 30 days and no less than five days prior to the patient's scheduled surgery to allow time for testing, processing, and shipping of the autologous components. Due to specific autologous requirements, autologous donations should ideally be scheduled at least 2 weeks before surgery.

Autologous donors must pay the fees for autologous units at the time of donation. Unfortunately, the fees will not be refunded if the unit(s) is not used. Please refer to your current Blood Service Agreement for cost information pertaining to collections of autologous blood products

Autologous donations are accepted at <u>select</u> Carter BloodCare Neighborhood Donor Centers Monday through Thursday, <u>by appointment only</u>. Walk-ins at the donor centers **will not** be accepted. Donors must present at the time of donation:

- Documentation to verify his/her SSN*
- A valid, unexpired photo ID

*NOTE: In the event that the patient does not have a SSN, please contact the Special Donations department as soon as possible to coordinate which identification number will be used.

6.1.4 Facility Notification of Autologous Donation

Following collection of an autologous donation, the Special Donations department faxes a copy of form SDF801.01B, Autologous Worksheet, to the facility that will receive the autologous component. The worksheet serves as facility notification that an autologous unit has been collected for the patient. The worksheet lists the patient's name, patient information, and the unit numbers of autologous units collected for the patient.

*NOTE: In the event of an unsuccessful autologous donation attempt, form SDF801.01C, Donation Attempt Notification Letter to Hospital, will be provided to the requesting facility and physician of record.

6.1.5 Autologous Labeling

Autologous components are labeled with the following:

- A green autologous tie tag is attached to the component bag.
- The front of the tag contains:
 - Information required if the component is a low weight/volume component
 - Eye-readable unit number

- ABO/Rh label
- The back of the tag contains patient information that is verified against the Autologous Blood Donation Request form. The following information is recorded:
 - Collection Date
 - Donation Identification Number
 - Pre-payment status
 - Patient Name
 - Sex
 - Date of Birth
 - Social Security Number
 (NOTE: If other identification number used instead of SSN, please coordinate number with Special Donation's department ASAP.)
 - Hospital
 - Surgery Date
 - Physician Name
 - Donor signature
- A copy of a green autologous tie tag is included at the back of this section.

6.1.6 Low Weight/Volume Autologous Red Cells

If the volume of whole blood collected is considered low volume, the weight of the unit is recorded on the front of the green autologous tie tag. Only packed red blood cells may be prepared from low volume units.

6.1.7 Autologous Unit Testing

All autologous units are tested for the following tests. Units are not released until all required testing is complete.

- ABO blood type
- Rh (D) blood type
- Total Cholesterol
- Hepatitis B Core Antibody (HBc)
- Hepatitis B Surface Antigen (HBsAg)
- Hepatitis C Antibody (HCV)
- HIV-1/2 Antibody (HIV-1/2)
- HTLV-I/II Antibody (HTLV-I/II)
- Indirect Antiglobulin Test (IAT)
- Serological Test for Syphilis (STS)
- Anti-*T-Cruzi*,(Chagas'), one time testing per donor
- Nucleic Acid Amplification testing (NAT) for HIV-1, HCV, HBV
- Nucleic Acid Amplification testing (NAT) for West Nile Virus (WNV)

Any abnormal test results are reported to your facility and the patient's physician on form SDF802.01A, Autologous Blood with Abnormal Test Results Notification, prior to product shipment. A copy of the notification form is included in this section. The donor is also notified directly by Carter BloodCare of any clinically significant results or results that would cause the donor to be deferred.

Confirmatory or supplemental testing is automatically performed on any reactive viral marker tests. These test results will be provided to the patient's physician.

Autologous units with confirmed HBsAg, anti-HIV 1/2, anti-HTLV I/II and/or NAT, will <u>not</u> be routinely sent to your facility. Such units will be discarded unless the physician requests delivery in writing. In the event that the unit tests positive for one or more of these tests, the Special Donations department will contact your facility to obtain approval for delivery or discard, unless a standing policy has previously been established. Units' positive for NAT WNV will not be available for transfusion. Units' positive for infectious disease markers sent to facilities for transfusion will be labeled with a Biohazard label.

Units with other positive tests will automatically be shipped to the patient's healthcare facility unless the facility notifies Carter BloodCare's Special Donations department that the facility will not accept shipment of autologous units with specific reactive laboratory tests. Units with reactive viral marker test results will be labeled with a Biohazard label.

6.1.8 Special Considerations

In the event, for any reason, an autologous unit is not available to be shipped, the Special Donations department will notify your facility and the patient's physician as soon as possible.

6.1.9 Policy for Freezing Autologous Red Blood Cells

Carter BloodCare will freeze autologous red blood cells based on the following:

- The patient has a rare blood type or multiple alloantibodies or other serological problems.
- The patient will need blood for a procedure that cannot be scheduled (i.e., delivery of a baby or awaiting cadaveric renal transplantation).
- The patient has had surgery postponed and will be unable to donate again due to a medical condition (i.e. patient with infection).
- To salvage a unit that has been air-contaminated, if time permits (at no charge to the hospital).

Carter BloodCare will not freeze the following:

- Whole blood
- Red blood cells with reactive infectious disease test results.

To freeze an autologous red cell component:

- The patient's physician must submit a written order to freeze the autologous red cells. The physician's office completes form SDF801.01E, Frozen Autologous Red Blood Cell Management Record, and submits it to the Special Donations department by fax or mail.
- Carter BloodCare's medical staff must approve the freeze procedure if it does not meet the above criteria.
- The Special Donations department will notify your facility of the request to freeze, by faxing the form to your facility.
- The healthcare facility must sign the form, accepting responsibility for any associated fees and return the form to the Special Donations department.
- The Special Donations department will make any necessary arrangements to return the component to Carter BloodCare for freezing.

Unless otherwise specified, frozen units will be discarded 90 days from the date frozen. If the unit is to remain frozen for longer than 90 days, an additional storage fee will be charged. Units with rare blood types or complicated serological problems may be frozen for extended periods of time without incurring additional fees. Please call for more information on freezing autologous red cell components.

6.2 RESTRICTED DONATIONS

Restricted donations are directed components collected from donors who have not met regular donor eligibility requirements, but have been approved by Carter BloodCare's medical staff for collection and transfusion into an intended recipient. These units <u>are not crossed over into regular inventory</u>. Restricted components have an orange tie tag, stating the donation is "RESTRICTED" and should not be crossed over into regular inventory, attached to the component bag. An example of a Restricted Donation tie tag is included at the back of this section. Restricted red blood cells may be frozen depending on the nature of the component and the medical condition (see 'Policy for Freezing Autologous Red Blood Cells' in the Autologous Policies Section).

Restricted blood donors must pay a handling fee for restricted units at the time of donation. Unfortunately, the fees will not be refunded if the unit(s) is not used for the patient. Please refer to your current Blood Service Agreement for cost information pertaining to collection of autologous or directed blood products

Restricted units may not be crossed over into regular inventory and upon release from the facility and return to Carter BloodCare will be properly discarded.

6.3 THERAPEUTIC PHLEBOTOMY

6.3.1 Therapeutic Donor Request

Form, SDF801.03, Therapeutic Donor Request, must be received by the Special Donations department <u>at least 5 business days</u> prior to the desired date of phlebotomy. If enrolling donor/patient into Carter BloodCare's hereditary hemochromatosis (HH) or testosterone replacement therapy (TRT) programs, please refer to section 6.5 for instructions. The order must include the following information:

- Patient name, gender, DOB and ID number (please <u>do not</u> provide social security number)*
- Patient phone number with area code*
- Patient diagnosis* (no ICD codes are accepted)
- Frequency of phlebotomy
- Target hemoglobin if less than 12.5g/dl*
- Pre-assessment completed by physician*
- Physician name, signature, date, phone & fax numbers *

Therapeutic donations will be limited to **whole blood phlebotomies only** (no automated procedures). If more than one unit (approximately 500mls) is required, the patient will need to present on additional visits to complete the required number of blood draws.

The request is valid for one year unless otherwise specified, and must be updated annually. The order is maintained on file at Carter BloodCare for the duration of validity.

6.3.2 Therapeutic Donation Criteria

It is not necessary for therapeutic donation candidates to meet all usual blood donor criteria such as weight and hemoglobin. Because the therapeutic donor may not be in optimal health at the time of collection, a signed consent form from the patient's regular physician may be required. The consent must originate from the patient's primary care physician (PCP) or physician that treats the patient's disorder or concern. Conditions requiring consent include history of cardiovascular problems, current pregnancy or any significant bleeding problems. The consent must be faxed to Special Donations along with the Therapeutic Donor Request at least 5 business days before anticipated date of phlebotomy.

6.3.3 Therapeutic Phlebotomy Scheduling

Once the Therapeutic Donor Request has been approved by the Special Donations department, a staff member will contact the patient to schedule the phlebotomy at one of our neighborhood donor centers. Appointments are scheduled Monday through Friday. Walk-ins will not be accepted.

^{*}Required fields – Request will be returned if all fields are not completed.

6.3.4 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.

6.3.5 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.

6.4 Hereditary Hemochromatosis (HH) and Testosterone Replacement Therapy (TRT) Programs

6.4.1 Donor Meets Eligibility Criteria and has a Draw Frequency of >8 Weeks

Patients diagnosed with Hereditary Hemochromatosis (HH) or receiving Testosterone Replacement Therapy (TRT) and require phlebotomy may qualify to have their units used for transfusion through special programs. If you are not eligible to donate due to known conditions such as HIV or Hepatitis, or due to cardiac or health issues, please see section 8.5.2. Donors with severe cardiac issues or other severe medical conditions may be referred to their physician for phlebotomy.

The HH program requires an initial prescription (refer to form DNF104.35C) to enroll in the program. Once the initial prescription has been received and approved by Donor Notification Department, enrollment notification will be sent by email or letter. If the donor meets all eligibility donor criteria and needs to donate once every 8 weeks or greater, they can donate at any donor center or mobile drive. After enrollment, they can schedule appointments online, by calling 817-412-5830, or as a walk-in.

The TRT program does not require a prescription if the donor meets all eligible donor criteria and needs to donate once every 8 weeks or greater. Donations can be made at a donor center or mobile drive. Donors can schedule appointments online, by calling 817-412-5830, or as a walk-in. Being on TRT is not a reason for deferral.

6.4.2 Donor Does not meet Eligibility Criteria &/or Requires a Draw Frequency of <8 weeks

HH and TRT donors that do not meet eligibility criteria or need to be drawn more often than 8 weeks, need a current prescription (refer to forms DNF104.35D and DNF104.35C). The prescription allows the donor to donate as frequently as once every 2 weeks. Frequency to be determined by the donor and their physician. Once the prescription has been received and approved by the Donor Notification Department, enrollment notification will be sent by email or letter. Donors can donate only whole blood at a donor center. Donors can schedule appointments by calling 817-412-5830. Prescriptions expire 12 months from the date signed by the physician.

For more information, please visit carterbloodcare.org

6.5 Special Donation Example Forms

6.5.1 Autologous Forms

- SDF801.01, Autologous Blood Donation Request
- SDF8001.01B, Autologous Worksheet
- SDF801.01C, Donation Attempt Notification Letter to Hospital
- SDF802.01A, Autologous Blood with Abnormal Test Result Notification
- SDF801.01E, Frozen Autologous Red Blood Cell Management Record
- DCL255, Autologous Tie Tag (double sided)
- Autologous Donation Information

6.5.2 Restricted, Therapeutic, HH and LOT Forms

- DCL500, Restricted Donation tie tag (orange)
- SDF801.03, Therapeutic Donor Request
- Therapeutic Donation Information
- DNF104.35C Enrollment/Prescription for No-Fee Phlebotomy for Hereditary Hemochromatosis (HH) Patients Only
- DNF104.35D Enrollment/Prescription for Phlebotomy Due to Testosterone Replacement Therapy (TRT)