FRESH WHOLE BLOOD (FWB) TRANSFUSION

Original Release/Approval		Oct 2006	Note: This CPG requires an annual review.
Reviewed:	Oct 2012	Approved:	24 Oct 2012
Supersedes:	Fresh Whole Blood (FWB) Transfusion, updated 17 Jul 2012		
☐ Minor Changes (or)		☒ ***Changes are substantial and require a thorough reading of this CPG (or)***	
☐ Significant Changes			

1. **Goal.** Provide the rationale and guidelines for FWB transfusion, including but not limited to indications, collection, testing, transfusion, and documentation.

2. **Background.** Whole blood has been used extensively to resuscitate casualties in military conflicts since World War I. Its use in civilian settings is limited due to the wide availability of fractionated components derived from whole blood and provided for specific deficits (e.g., packed red blood cells (RBCs) for anemia, fresh frozen plasma (FFP) to replace lost/consumed clotting factors, apheresis platelets (PLTs) for thrombocytopenia, cryoprecipitate (Cryo) for hypofibrinoginemia.) However, in austere conditions, fractionated blood products may be in limited supply or unavailable. In these settings, FWB may be the only source of blood components available for the management of hemorrhagic shock and its associated coagulopathy in casualties. (Appendix A, Blood Donor Pre-Screening SOP).

   Massively transfused casualties (≥ 10 units RBCs in 24 hours) have a high mortality rate (33%) and have the greatest potential to benefit from appropriate transfusion strategies.[1] Large retrospective cohort studies of casualties requiring massive transfusions during Operations IRAQI FREEDOM (OIF) and ENDURING FREEDOM (OEF) demonstrate a significant survival benefit for the massively transfused casualty when RBCs, fresh frozen plasma, and platelets are transfused at a 1:1:1 ratio. Two retrospective analyses in combat casualties comparing FWB to component therapy (which included platelets) have been published. One study showed a potential survival benefit to the use of FWB during resuscitation of severe combat injuries, and the other showed FWB to be equivalent to component therapy.[2, 3]

   Advantages to FWB: FWB provides FFP:RBC:PLTs in a 1:1:1 ratio. For US casualties presenting in hemorrhagic shock, a transfusion strategy that included FWB with RBCs and plasma has an improved survival compared to the use of stored components only (FFP, RBCs, and PLTs). Additionally, FWB is available in austere conditions, has no loss of clotting factor or platelet activity that is often associated with cold storage, and has no red blood cell "storage lesion".

   Disadvantages to FWB: Since FWB has both RBCs and plasma, it must be ABO type-specific. There are risks associated with the use of FWB, including but not limited to increased risk of transfusion-transmitted infections (e.g., HIV, hepatitis B/C, syphilis), a period of decreased exercise tolerance in donors (who are often members in the casualty's unit), and an increased risk of clerical errors (e.g., ABO typing) due to the potentially chaotic activity during which FWB is requested. Additionally, field conditions are inherently unsanitary and are presumed to increase the risk of bacterial contamination of the blood. Recent history with approximately 10,000 FWB transfusions to U.S. personnel during

OIF/OEF have resulted in one Hepatitis C (HCV), one Human T-Lymphocyte Virus (HTLV) seroconversion, and one fatal case of transfusion-associated graft-versus host disease.[4]. Fresh WB is not FDA-approved and is not intended or indicated for routine use. **It is NOT appropriate, as a matter of convenience, to use FWB as an alternative to more stringently controlled blood products for patients who do not have severe, immediately life-threatening injuries. FWB is to be used only when other blood products are unable to be delivered at an acceptable rate to sustain the resuscitation of an actively bleeding patient, when specific stored components are not available (e.g., pRBCs, PLTs, Cryo, FFP), or when stored components are not adequately resuscitating a patient with an immediately life-threatening injury.**

3. **Recommendations**. The use of FWB should be reserved for casualties who are anticipated to require massive transfusion (10 or more units pRBCs in 24 hours), for those with ***clinically significant shock or coagulopathy (e.g. bleeding with associated metabolic acidosis, thrombocytopenia or INR>1.5) when optimal component therapy (e.g. apheresis platelets and FFP) are unavailable or stored component therapy is not adequately resuscitating a patient with immediately life-threatening injuries.***

   a. *Facilities where full component therapy is available:* Due to infectious concerns, the risk:benefit ratio does not justify the routine use of FWB over banked blood products in non life-threatening severe trauma. Conversely, when platelets and FFP inventories are depleted, or in contingencies such as mass casualty (MASCAL) situation where the blood inventory may be exhausted, the use of FWB remains an appropriate life-saving option.

   b. Surgical Facilities where component therapy is limited (e.g. no availability of apheresis platelets): Due to risks inherent with the use of FWB it should only be used for patients *with immediate life-threatening injuries.*

   c. *Facilities where full component therapy is not available:* FWB should only be used when there is a threat to loss of life, limb or eye-sight.

4. **Guidelines**. The decision to use FWB is a medical decision that must be made by a physician who has full knowledge of both the clinical situation and the availability of compatible blood components. A Walking Blood Bank (WBB) Program will be established based on a risk assessment and the potential for casualties. Coordination with the Area Joint Blood Program Officer (AJBPO) is required to establish a WBB Program. (Appendix A, Blood Donor Pre-screening SOP). FWB should be collection for transfusion as outlined in Appendix B, Emergency Whole Blood Drive SOP.

   a. In general, the use of FWB should be limited to casualties who are anticipated to require a massive transfusion when the physician determines that optimal component therapy is unavailable or in limited supply, or in patients that are not responding to stored component therapy.

   b. The decision to initiate a FWB drive should be made in consultation with the appropriate MTF medical authority (e.g., DCCS, Trauma Director) and Laboratory/Blood Bank OIC.

   c. Pre-screened donors registered into the WBB Program are preferably composed of active duty, active reserve, active National Guard, and other DoD beneficiaries. Coalition Forces will not be utilized routinely as donors, only by exception. Foreign Nationals should be used as a last resort.

d. Donor FWB must be an ABO type-specific match to the casualty. If not matched, a fatal hemolytic reaction may occur. **TYPE O whole blood is NOT universal.**

e. **The decision to use FWB that has not been completely screened for infectious agents is a medical decision that must be made after thorough consideration of risks and benefits. Decision-making should be adequately documented in the casualty record**.

f. Prior to issuing FWB for transfusion, the ABO and Rh type should be verified and approved rapid infection disease tests (e.g., HIV, HCV, and HBV) should be performed as outlined in Appendix B, Emergency Whole Blood Drive SOP to the greatest extent possible.

g. Theater Medical Data Stores (TMDS), Blood Portal, shall be utilized to record FWB donations and infectious disease testing results.

5. Precautions. Transfusion of FWB in the field may be dangerous for several reasons:

a. There is no universally compatible FWB type. Transfusions of FWB must be an ABO match. For female casualties of child-bearing potential, there must also be an Rh match. Service members' blood types are not always known with certainty. The blood type on identification tags is occasionally incorrect (last correlated data equated to about 4%) and must not be relied upon routinely to determine blood type for either donors or recipients. **Identification tags for ABO/Rh verification should be utilized as a last resort only.**

b. Because it is not subject to the same infectious disease testing and strict quality controls as banked blood, FWB does not meet FDA standards and has an increased risk of transfusion-transmitted infections (e.g., HIV, hepatitis B/C, syphilis).

c. In MASCAL situations, particularly when more than one blood type is being collected, there is an increased risk of a clerical error leading to a life-threatening transfusion reaction.

d. Field conditions are inherently unsanitary and increase the risk of bacterial contamination of the blood.

e. Use of non-standard blood donation material and equipment may lead to coagulation during the collection process potentially causing an adversely transfusion reaction; therefore, only authorized equipment will be utilized (Appendix B enclosure 6, WBB Supply List (with NSNs)).

6. Planning. Since the need for FWB cannot be predicted, a robust contingency operational plan should be developed by the MTF staff to include the Laboratory/Blood Bank and surgical and anesthesia providers in coordination with the Area Joint Blood Program Officer. The plan should be reviewed and rehearsed regularly.

The key elements for planning and readiness to administer FWB are knowledge and rehearsal of two SOPs: Appendix A, Blood Donor Pre-Screening SOP and Appendix B, Emergency Whole Blood Drive SOP.

a. A contingency plan should be developed for collecting, storing, and transfusing FWB in MASCAL situations or when it may be deemed the current blood inventory will be exhausted prior to re-supply (e.g., when multiple type-O trauma casualties are exhausting the type-O RBC inventory).

b. The physical donation site should be organized in such a way as to maintain the integrity of the screening and donation process, and to minimize the possibility of clerical errors. This is especially important in emergency situations involving more than one casualty.

c. Every effort should be made to adhere to the same screening, drawing, labeling, and issuing standards required for U.S. FDA-approved blood products.

d. Pre-screened donors in the WBB Program determined to be suitable should be utilized before using personnel who: (1) are not fully suitable; (2) do not have a current screening and infectious disease testing history; (3) have no donation history, to the greatest extent possible.

e. Upon determining the ABO/Rh status of the casualty, activate the WBB Program re-calling pre-screened donors with the exact same ABO/Rh using the TMDS>Manage Donor>View Donor List, if available, or other communication networks.

f. Before any FWB is transfused, rapid infectious disease testing (i.e., HIV, HBV, HCV) of donor specimens shall be performed, to the greatest extent possible.

g. Retrospective samples must be sent to a state-side laboratory for FDA-approved testing, regardless whether the rapid infectious disease testing is performed pre- or post-transfusion, as these tests are not licensed for donor testing.

h. Upon the notification of confirmed positive infectious disease results, a medical provider or preventive medicine personnel should be notified to ensure the donor is notified and counseled.

i. If a patient receives a confirmed positive infectious disease unit, the AJBPO will notify the Armed Services Blood Program immediately to initiate patient notification and a respective evaluation of both the donor and patient.

j. In accordance with HA Policy 10-002, *Policy on the Use of Non-U.S. Food and Drug Administration*, recipients of FWB shall receive follow-up infectious disease testing as soon as possible, 3-, 6-, and 12-months post-transfusion.

k. A contingency plan should be developed for collecting, storing, and transfusing FWB in MASCAL situations or when it may be deemed the current blood inventory will be exhausted prior to re-supply (e.g., when multiple type-O trauma casualties are exhausting the type-O RBC inventory).

l. **Procedure**. See Appendix B for DD Form 572–Emergency Whole Blood Donation Record.

7. Performance Improvement (PI) Monitoring.

a. Intent (Expected Outcomes).

FWB is reserved for casualties who are anticipated to require massive transfusion (10 or more units of RBCs in 24 hours), for those with clinically significant shock or coagulopathy (e.g., bleeding with associated metabolic acidosis, thrombocytopenia or INR >1.5) when optimal component therapy (e.g., PLTs and FFP) are unavailable or stored component therapy is not adequately resuscitating a patient with immediately life-threatening injuries.

b. Performance/Adherence Measures.

1) FWB was used for casualties who were anticipated to require massive transfusion (10 or more units of RBCs in 24 hours), for those with clinically significant shock or coagulopathy (e.g., bleeding with associated metabolic acidosis, thrombocytopenia or INR >1.5) when optimal component therapy (e.g., PLTs and FFP) was unavailable or stored component therapy was not adequately resuscitating the patient with immediately life-threatening injuries.

c. Data Source

1) Patient Record

2) Joint Theater Trauma Registry (JTTR)

3) Blood transfusion databases

d. System Reporting & Frequency.

The above constitutes the minimum criteria for PI monitoring of this CPG. System reporting will be performed annually; additional PI monitoring and system reporting may be performed as needed.

The system review and data analysis will be performed by the Joint Theater Trauma System (JTTS) Director, JTTS Program Manager, and the Joint Trauma System (JTS) Performance Improvement Branch.

8. Responsibilities. It is the trauma team leader's responsibility to ensure familiarity, appropriate compliance and PI monitoring at the local level with this CPG.

9. References:

1. Repine TB, Perkins JG, Kauvar DS, Blackborne L. The use of fresh whole blood in massive transfusion. *J Trauma.* 2006;60:S59-S69.

2. Spinella PC, Perkins JG, Grathwohl JG, Beekley AC, Holcomb JG. Warm fresh whole blood is independently associated with improved survival for patients with combat-related traumatic injuries. *J Trauma.* 2009;66:S69-S76.

3. Perkins JG, Cap AP, Spinella PC, Shorr AF, Beekley AC, Grathwohl KW, Rentas FJ, Wade CE, Holcomb JB; 31st Combat Support Hospital Research Group. Comparison of platelet transfusion as fresh whole blood versus apheresis platelets for massively transfused combat trauma patients (CME). *Transfusion*. 2011 Feb;51(2):242-52.

4. Gilstad C, Roschewski M, Wells J, Delmas A, Lackey J, Uribe P, Popa C, Jardeleza T, Roop S. Fatal transfusion-associated graft-versus-host disease with concomitant immune hemolysis in a group A combat trauma patient resuscitated with group O fresh whole blood. *Transfusion*. 2012 May;52(5):930-5.

5. CENTCOM FRAGO 09-1222: *Joint Theater Blood Program Update*: 4 May 2007.

6. *Emergency War Surgery*, 2004, Third US Revision, Chap 7: Shock and Resuscitation.

7. Theater MTF-specific Standard Operating Procedures (SOPs).

8. *Technical Manual*, AABB, Bethesda Maryland, 16th Edition, 2008.

9. *Standards for Blood Banks & Transfusion Services*, AABB, 25th Ed, February 2008.

10. Theater Medical Data Stores (TMDS), Blood Portal, Standard Operating Procedures (http://militaryblood.dod.mil/Staff/eMOAS.aspx).

Approved by CENTCOM JTTS Director, JTS Director and CENTCOM SG

Opinions, interpretations, conclusions, and recommendations are those of the authors and are not necessarily endorsed by the Services or DoD.

APPENDIX A

Blood Donor Pre-Screening SOP

Materials and Equipment	Use the following materials and equipment as applicable. • Modified DD Form 572s • Clip Boards • Gloves • Testing Collection Set: premade bags with 2x2 gauze, 2 gold tops (SST), 2 pearl tops (PPT), 1 purple top tube (more tubes may be required if using short draw or small volume tubes) • Blood Collection Needles • BD Vacutainer Hubs • Coban • Assigned Pre Screen ISBT Labels (500 number series) • Sharps Containers • ABO/Rh Testing Card (e.g., Eldon Military Kit or other FDA-approved device) • Centrifuge • Disposable Pipettes • Plastic Aliquot tubes/lids 13X100mm (or 12X75mm) • Para-Film • Biohazard Bags • Trash Bags • Leak Resistant Chucks • Disposable Lab Coats • Cold Packs • Test Tube Racks
Records/Forms	• Modified **DD FORM 572**, Form 147, Form 148 (See Enclosures—Blood Donor Pre-Screening SOP.) • Theater Medial Data Store (TMDS), Blood Portal
Quality Control	Perform QC on ABO/Rh Testing Card (See instrument package inserts for procedures). Medical personnel should be trained by BSD or other qualified personnel.
Procedure	**Pre-screening of a prospective emergency whole blood donor pool is mandatory. Development of a pre-screened donor pool should be considered a commander's priority when a level II or III facility is established or replaced. It is imperative that a donor pool once established is maintained because of the frequent redeployment of units out of theatre. Due diligence in establishing a pre-screened whole blood donor pool will decrease the risk of transmitting infectious disease while simultaneously increasing the efficiency of the whole blood collection process.** Perform the following steps when Pre-screening Donors:
	Prepare for Donor Pre-Screening Event
	1. Coordinate with appropriate units/contacts for times and location of event. May need to conduct a site survey to ensure appropriate site, i.e., space, lighting, privacy for interview, etc. Samples need to be sent to the blood support detachment as soon as possible after collection, so prior coordination with transport assets is a must.

Blood Donor Pre-Screening SOP

	Conducting the Pre-Screening Event		
	1.	**Medical History**-Provide prospective donor a Modified DD Form 572 – ensure demographic info is legible and as complete as possible.	
	2.	**Interview**-Trained medical personnel will need to determine if the donor is eligible to donate based on the information collected –Donor eligibility requirements. can found on the Blood Portal at: http://rceast.afghan.swa.army.mil/sites/tfmeda/	
		If	**Then**
		There are all '**N**'o responses except for questions 22-24	Proceed to Step 3.
		There are any '**Y**'es responses except for questions 22-24	Document the reason for the 'Y'es response. Refer donor to a qualified provider (i.e., MD, DO, NP or PA) to determine the donor's eligibility. Defer the donor as required, if necessary document "Ineligible" status on **DD FORM 572** and in TMDS.
		NOTE: For Q: 39, use State Tattoo and Permanent Make-up Reference List. See Tattoo and Make-up Reference List to screen for acceptability.	
	3.	Using the Direct Oral Questions, ask the donor Group A, B, and C questions. Record name of interviewer on DD Form 572. See Enclosures—Blood Donor Pre-Screening SOP.	
		If	**Then**
		The donor answers '**N**'o to each group	Proceed to Step 4.
		The donor answers '**Y**'es to any group	Defer donor for designated period of time and stop the donation process. Document donor as "Ineligible".
	4	**Phlebotomy**- Collect 1 Purple Top, 2 Pearl Top (PPT), 2 Gold Top (SST) and label with small **Pre-Screen** (500 number series) ISBT labels (***without*** barcodes). Apply the same ISBT label number to the DD Form 572.	
	Register Donor in TMDS per Manage Donations/Donors SOP . See steps below.		
	Rapid Infectious Disease Testing. If performed, see Emergency Whole Blood Collection SOP for instructions**.**		
	Perform ABO/Rh Testing		
	1.	Utilizing blood from purple top tube, perform ABO/Rh confirmation using Eldon Card or other FDA-approved method to verify ABO listed on **DD FORM 572**. (Refer to package inserts and approved SOPs for further instructions).	
	2.	Record Lot # of reagents, EXP Date and Results on Form 147.	
	3.	Record blood type in TMDS.	
	See Enclosures—Blood Donor Pre-Screening SOP.		

Blood Donor Pre-Screening SOP

	Processing Samples for Shipment & Testing	
	1.	Centrifuge Gold Top and Pearl Top Tubes for 5 minutes at 4000 RPM.
	2.	Label aliquot (pour off) tubes with corresponding ISBT Labels ***with small*** **barcodes**. Position the ISBT label vertically toward top of tube as shown at left. **If ISBT labels are not available utilize the Donor SSN as the unit number.** 
	3.	Pour 1 Pearl Top into 1 aliquot tube and mark as **Plasma**. Repeat for each Pearl Top tube. ***3ml sample requirement per aliquot.**
	4.	Pour contents of 2 Gold Top tubes into 1 aliquot tube and mark as **Serum**. * Do not fill over ¾ full to allow for expansion from freezing
	5.	The seal of capped aliquot tubes should be reinforced with para-film wrap and placed into a biohazard shipping bag or rack. If a rack is not used, rubber-band tubes from the same donor together. Repeat for each series.
	6.	Record sample and donor demographic data on Form 148 (Shipping Manifest). Include a printed copy of manifest with shipment and e-mail to BSD or designated facility, if possible.
	7.	Maintain the (pre-screening) **DD FORM 572**s at your site until the potential donor redeploys. As soon as possible ship samples, and Form 148 in a blood box (Collins Blood Box) with ice bag(s) to your respective blood detachment. E-mail a copy of manifest to BSD or designated facility, if possible, or call to alert incoming shipment. **For Afghanistan**: Blood Support Detachment TF MED/Bagram Airfield APO AE 09354 (BAF) 431-5446/5536 Blood Support Detachment Kandahar Air Field APO AE 09355 (KAF) 421-6171 **For other deployed units**. Freeze samples until they can be shipped to a designated laboratory to perform FDA-approved testing.
	8.	The BSD or unit will send all samples for FDA-approved testing to designated laboratory for FDA-approved testing. Enter results in TMDS and forward to submitting Level II or Level III upon completion. **NOTE: The prospective donor is NOT considered pre-screened and fully qualified for FWB donation until negative or non-reactive testing results are received from a testing facility.**
	9.	Any positive testing that is received by BSD or unit will be forwarded to Preventive Medicine Consultant to ensure proper donor care and follow-up is initiated. At no time will laboratory staff notify donors directly regarding positive testing results.

Blood Donor Pre-Screening SOP

	Maintain Database (TMDS)	
	1.	Transfer demographic information from the **DD FORM 572** and Form 147 to Donor Management Database in TMDS. This will act as a deferral list or an eligible donor list when a whole blood drive is necessary. It is recommended that a hard copy of Donor Database and deferral list be printed monthly (or at some regular interval) for use during Emergency Whole Blood Collection when computer assets are unavailable. **Information in database should be kept confidential.**
	2.	To enter demographic data into TMDS, go to the **Manage Donation** tab and select **Donate Product**. Enter the Donor SSN, first name, last name in appropriate fields and click **NEXT**.
	3.	In product code field, enter **E9999V00** (pre-screen). In the expiration date field, enter date 90 days from today and click **Add Product**.
	4.	Verify donation ID, product code, ABO/Rh and expiration date are correct, then click **NEXT**.
	5.	Carefully Re-verify all demographic data that populates on the screen, then click **Confirm Donation**. Prospective donor is now entered in TMDS.
	6.	From **Manage Donation** tab, select **Update Donation.** Enter donation ID number and click **NEXT.**
	7.	Enter ABO/Rh test result and date tested from Form 147 under Rapid Testing Results. In "Samples sent to" field, select BSD or unit from pull down menu and enter date samples were sent out from your facility. Now click **Update Tests**.
	8.	To Register another donor, select **Donate Product** under **Manage Donation** tab and repeat process above.
	9.	Once pre-screen donations have been created utilizing the process above, a re-deployment date must be entered to ensure the active donor list will auto-update upon donor's exodus from theater. To accomplish this, select Manage Donor from beneath Manage Donor tab. Enter donor SSN and click Next. Select re-deployment date from the calendar tool in the "Update Re-deployment Date" field and click Update Donor. Once the displayed entry is confirmed to be correct, click Confirm Update. TMDS will now remove donor from active donor list on the re-deployment date that was entered.
	10.	BSD will populate FDA results and forward to submitting facility. Donor alerts will also be activated by BSD or unit, as necessary. This data once populated, will be the basis by which potential donors will be deemed fully qualified for Fresh Whole Blood (FWB) donations, should the need for a Walking Blood Bank (WBB) arise at your facility.
	NOTES: Investing time and care into building a donor pool will make performing whole blood drives easier and safer when the time comes. Your donor pool does not need to be enormous. 50 people covering most of the blood types (O, A, B) is ideal for most locations. **!!!REMEMBER WHOLE BLOOD MUST BE TRANSFUSED TYPE SPECIFIC!!!**	
References	1. AABB *Technical Manual*, current edition 2. AABB *Standards for Blood Banks and Transfusion Services* 3. JTTS Clinical Practice Guideline: Fresh Whole Blood (FWB) Transfusion 4. Theater Medical Data Store (TMDS) Version 2.7.0.0 System User's Manual	

Blood Donor Pre-Screening SOP

Enclosures	DD Form 572-Emergency Whole Blood Donation Record Approved State Tattoo and Permanent and Make-up Reference List Direct Oral Questions Form 147–Eldon Card ABO/Rh Typing Record Form 148–Pre-Screen/Whole Blood Sample Shipping Manifest

DD FORM 572—EMERGENCY WHOLE BLOOD DONATION RECORD

Please circle as appropriate:
WHOLE BLOOD DONATION
PRE-SCREEN

EMERGENCY WHOLE BLOOD DONATION RECORD
(Modified Version of the DD Form 572)

Blood Unit Number
Use Donor SSN if ISBT # Not Available

MTF/Location: _____ Donation Date: _____

Donor's Full Name: _____ Rank: _____ Branch: USA USAF USN USMC CIV

SSN: _____ Date of Birth (DDMMMYYYY): _____ Sex: M / F Ht/Wt: _____ (> 110 lbs) ABO/Rh (Blood Type) :_____

Deployed Unit/Location: _____ Local DSN Phone: _____ Local Cell/ Evening Phone_____
Redeployment Date: _____
Current Residence: Bldg/Tent # _____ RM # _____
Home Address (Stateside) _____
Home Phone Number: (____) _____ Email: _____

Y 21. N	Female Donors: Are you pregnant now, or have you been Pregnant in the last 6 weeks?	Y 36. N	Have you ever had Chagas' disease, babesiosis, or Leishmaniasis?
Y 22. N	Are you feeling well and healthy today?	Y 37. N	In the past 12 months, have you been given a rabies shot?
Y 23. N	Have you read and do you understand all the donor information presented to you, and have all your questions been answered?	Y 38. N	In the past 12 months, have you had an accidental needle stick or come in contact with someone else's blood?
Y 24. N	Do you understand that if you are in a high risk group, you may have the AIDS virus and you can give it to someone else even though you may feel well and have a negative AIDS test?	Y 39. N	In the past 12 months, have you had a tattoo, ear or skin piercing, or acupuncture?
Y 25. N	Have you ever given blood under another name or Social Security Number?	Y 40. N	In the past 12 months, have you had close contact with a person with yellow jaundice or hepatitis or been given Hepatitis B Immune Globulin (HBIG)?
Y 26. N	In the past 8 weeks have you given blood, plasma or platelets?	Y 41. N	Have you ever had yellow jaundice, liver disease, hepatitis, or a positive test for hepatitis?
Y 27. N	Have you ever been refused as a blood donor or told not to donate blood?	Y 42. N	In the past 4 weeks, have you had any shots or vaccinations?
Y 28. N	In the past 12 months have you been under a doctor's care, had an illness, or surgery?	Y 43. N	In the past 8 weeks, have you received a smallpox vaccination or had close contact with the vaccination site of anyone else?
Y 29. N	In the past 12 months, have you received blood, blood products, or a tissue transplant including any you may have donated for yourself (autologous)?	Y 44. N	In the past month, have you taken Finasteride (Proscar, Propecia) or Isotretinoin (Accutane, Amnesteem, Claravis, Sotret) or in the past 6 months, have you taken Dutasteride (Avodart)
Y 30. N	In the past 3 years, have you had malaria?		
Y 31. N	In the past month, have you taken any pills or medications?		
Y 32. N	Have you ever been given growth hormone or received a dura mater (or brain covering) graft?		
Y 33. N	Have you ever taken Etretinate (Tegison) or Acitretin (Soriatane)?		
Y 34. N	Have you ever had cancer, a blood disease, or a bleeding problem?		
Y 35. N	Have you ever had chest pain, heart disease, or lung disease?		

(Use this section and reverse side of form to explain "Yes" answers above. With the exception of questions 22-24)

High Risk Oral Questions (10 Jan 2010) Asked By: _____ Donor: Temp: _____°F/°C (< 99.6°F/37.5°C) BP: _____/_____ (≤ 180/100) Pulse: _____ (< 100 bpm) HCT/Hgb: _____ (> 38% or 12.5 g/dL)

31. Medications: _____

Malaria Prophylaxis: Daily_____(Doxycycline) Weekly_____(Mefloquin) N/A _____

Your blood will **NOT** be tested for viral diseases prior to transfusion due to the emergency, if you any reason you feel your blood may not be safe or you could answer yes to the high risk questions, please do not donate today. I have read/ had explained to me the high risk questions and am not in a high risk category, and feel my blood is safe to donate at this time.

I verify that I have answered the questions honestly, and feel my blood is safe to be transfused. _____
Donor's Signature

Phlebotomist:_____ Start Time:_____ Stop Time:_____ (Should be < 15 minutes)

Bag Manufacturer _____Lot #:_____ Expiration date: _____ Segment Number: _____

The Modified DD Form 572 has been reviewed for completeness. If there are any risk factors that place the recipient at harm notify the ordering physician immediately for appropriate follow-up.

DD 572 (WB)
Version: 13 May 2010

APPROVED STATE TATTOO AND PERMANENT AND MAKE-UP REFERENCE LIST

Armed Services Blood Program
State Tattoo and Permanent Make-Up Reference List

NOTICE: The Department of Defense (DOD) assumes no risk for the use of this information by non-DoD personnel, blood programs, or individual medical institutions. The use of this information by DoD personnel is strictly for blood donor operations and must adhere to the current Service (Army, Navy and Air Force) specific Standard Operating Procedure dealing with the screening of blood donors.

NOTE: The following criteria provided by AABB Reference Standard 5.4.1A, Requirements for Allogeneic Donor Qualification, were used to determine acceptability of each state: (a) application by a state-regulated entity, (b) mandated use of sterile needles, (c) one-time use ink required.

If the state is acceptable, defer the donor for one week to ensure the site has properly healed. Although the state of application may be acceptable, prospective donors should be asked if the procedure was performed using sterile needles and single-use dye. If the donor answers no, or does not know, he/she should be deferred for 12 months. Prospective donors who had a procedure performed in a state listed as "No" must be deferred for 12 months from the time of application.

Armed Services Blood Program

State	Acceptable	Note
Alabama	YES	
Alaska	YES	
Arizona	YES	
Arkansas	YES	
California	NO	
Colorado	YES	
Connecticut	NO	
Delaware	YES	
District of Columbia	NO	
Florida	NO	

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Armed Services Blood Program

State	Acceptable	Note
Georgia	NO	
Hawaii	YES	
Idaho	NO	
Illinois	YES	
Indiana	YES	
Iowa	YES	
Kansas	YES	
Kentucky	YES	
Louisiana	YES	
Maine	YES	
Maryland	NO	
Massachusetts	NO	
Michigan	NO	
Minnesota	NO	
Mississippi	YES	
Missouri	YES	
Montana	YES	
Nebraska	YES	
Nevada	NO	
New Hampshire	NO	
New Jersey	YES	

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Armed Services Blood Program

State	Acceptable	Note
New Mexico	NO	
New York	NO	
North Carolina	YES	
North Dakota	NO	
Ohio	YES	
Oklahoma	NO	
Oregon	YES	
Pennsylvania	NO	
Rhode Island	YES	
South Carolina	YES	
South Dakota	YES	
Tennessee	YES	
Texas	YES	
Utah	NO	
Vermont	YES	
Virginia	YES	
Washington	YES	
West Virginia	YES	
Wisconsin	YES	
Wyoming	NO	

Revised Date: 14-Mar-12 BPL 12-01 BPL Date: 14-Mar-12 Page 3 of 3

DIRECT ORAL QUESTIONS

<table>
<tr><td>Preamble</td><td colspan="2">I am required to ask you some questions. If you do not understand a question, please ask me to explain it before answering. The reason for asking these questions is to determine your suitability as a volunteer blood donor. Your answers to these questions will be kept strictly confidential, but may result in you being asked not to donate blood, either temporarily or permanently. Do not respond until I have asked you the entire group of questions, which at that time only give me one answer – Yes or No.</td></tr>
<tr><td>Group A</td><td colspan="2">1. Do you have AIDS or have you ever had a positive test for the AIDS virus (HIV)?
2. Have you ever taken illegal drugs with a needle, even one time (including steroids)?
3. Have you ever taken clotting factor concentrates for a bleeding disorder such as hemophilia?
4. At any time since 1977, have you taken money or drugs in exchange for sex?
5. Male donors only: Have you had sex with another male, even one time since 1977?
A “Yes” answer to Group A is a PERMANENT DEFERRAL</td></tr>
<tr><td rowspan="11">Group B</td><td colspan="2">1. Were you born in, have you lived in, or traveled to any African country since 1977?</td></tr>
<tr><td>If response is</td><td>Then</td></tr>
<tr><td>No</td><td>Proceed to Group B, Question 3</td></tr>
<tr><td>Yes</td><td>Was it any of these countries: Cameroon, Benin, Central African Republic, Chad, Congo, Equatorial Guinea, Kenya, Gabon, Niger, Nigeria, Senegal, Togo or Zambia?</td></tr>
<tr><td>If No</td><td>Go to Group B, Question 3</td></tr>
<tr><td>If Yes – Travel Only</td><td>Proceed to Group B Question 2</td></tr>
<tr><td>If Yes – Born or Lived in</td><td>Document when, DEFER INDEFINITELY</td></tr>
<tr><td colspan="2">2. When you traveled to (name of country) did you receive a blood transfusion, or any other medical treatment with a product made from blood?</td></tr>
<tr><td>If response is</td><td>Then</td></tr>
<tr><td>No</td><td>Proceed to Group B, Question 3</td></tr>
<tr><td>Yes</td><td>DEFER INDEFINITELY</td></tr>
<tr><td colspan="2">3. Have you had sex with anyone who was born in, or has lived in any African Country since 1977?</td></tr>
<tr><td>If response is</td><td>Then</td></tr>
<tr><td>No</td><td>Proceed to Group C</td></tr>
<tr><td>Yes</td><td>Was it any of these countries: Cameroon, Benin, Central African Republic, Chad, Congo, Equatorial Guinea, Kenya, Gabon, Niger, Nigeria, Senegal, Togo or Zambia?</td></tr>
<tr><td>If No to listed countries</td><td>Proceed to Group C</td></tr>
<tr><td>Yes to listed countries</td><td>Document when, DEFER INDEFINITELY</td></tr>
</table>

Group C	1. Have you had sex in the last 12 months, even once, with anyone who has AIDS or has had a positive test for the AIDS virus? 2. Have you had sex in the last 12 months, even once, with anyone who has ever taken illegal drugs with a needle (including steroids)? 3. Have you had sex in the last 12 months, even once, with anyone who has taken clotting factor concentrates for a bleeding disorder such as hemophilia? 4. At any time in the last 12 months have you given money or drugs to someone to have sex with you? 5. At any time in the last 12 months, have you had sex with someone who has taken money or drugs in exchange for sex? 6. In the past 12 months, have you had a positive test for syphilis? 7. In the last 12 months have you had syphilis or gonorrhea or have you been treated for syphilis or gonorrhea? 8. In the last 12 months, have you received blood or blood products? 9. In the last 12 months, have you been incarcerated in a correctional institution (including jail or prison) for more than 72 consecutive hours? 10. In the last 12 months, have you taken (snorted) cocaine through your nose? 11. Female donors only: In the past 12 months, have you had sex with a man who had sex with another man, even one time since 1977? **A "Yes" answer to Group C is a TEMPORARY DEFERRAL for 12 months following the event**
Group D	1. Have you at any time since 1980 injected Bovine (Beef) Insulin? **A "Yes" answer to Group D is an INDEFINITE DEFERRAL**

FORM 147–ELDON CARD ABO/RH TYPING RECORD

Eldon Card ABO/Rh Typing

Date of Testing:__________.

	Eldon Card ABO/Rh Typing					
	Lot #					
	Exp:					Tech
Assigned Unit #	Anti-A	Anti-B	Anti-D	Rh Control	Interpretation	Initials
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		

Form 147
V: 28 June 2010

Technical Review: __________ Date: __________
QA/QC Review: __________ Date: __________

FORM 148–PRE-SCREEN/WHOLE BLOOD SAMPLE SHIPPING MANIFEST

Prescreen/Whole Blood Sample Shipping Manifest

Blood Unit Number					Donor Name								
Facility ID (W0138)	YR	Unit Id #	ABO RH	Donation Date	Last	First	Branch of Service	Nationality	SSN or ID #	DOB	FOB/Base	Unit	Donation Type (PS or FWB)

rm 148

APPENDIX B
EMERGENCY WHOLE BLOOD COLLECTION SOP

Materials and Equipment	Use the following materials and equipment as applicable: • Vitals Machine • Blood Collection Beds • Stethoscope • Blood Pressure cuff • Digital Thermometer and/or Tempadots • Lancets • STAT Site M* (*or other POCT Hemaglobinometer) • STAT Site M test cards* • STAT Site M controls* • Coban • Alcohol Pads • Electronic table top scale (optional) • Blood Bags (Terumo- Single Blood Bags, preferred) **NOTE: If an additive solution (AS) bag is present with a multiple bag set-up, the AS SHALL NOT be added to the whole blood.** • Blood Trip Scale with 585±2g trip counter-weight and QC weights or HemoFlow. • Testing Collection Set: premade bags with sterile 4x4 gauze, Frepp Sepp, 2 gold tops (SST), 2 pearl tops (PPT), 1 purple top tubes, and tube collection device. • ChloraPrep, Iodine alternative • Adapter MS DIR 100S Luer 100S • ABO/Rh Testing Card (e.g., Eldon Military Kit or other FDA-approved device) • Rapid HIV, Malaria, HBsAg, and HCV test kits • Serological RPR kit • Clinical Rotator • Centrifuge • Disposable Pipettes • Adhesive Tape • Hemostats • Scissors • Strippers • Metal Clips • Gloves • Tourniquet • Biohazard Container/ Sharps Container • Whole Blood ISBT Labels (100 number series)
Records/Forms	Forms required: modified **DD FORM 572**, Form 145A, Form 147, Form 148, Form 150A, Form 150B, Form 151 and SF 518 (as applicable.) See Enclosures-Emergency Whole Blood Collection SOP. Theater Medical Data Store (TMDS), Blood Portal.

EMERGENCY WHOLE BLOOD COLLECTION SOP

Quality Control	Perform QC on STAT Site M (or equivalent POCT Hemaglobinometer) Perform QC on ABO/Rh Testing Card, RPR, HCV, HBsAg, HIV, and Malaria Kits (See instrument package inserts and local SOPs for procedures.) Medical personnel should be trained by BSD or other qualified personnel.	
Procedure	Perform the following steps when the physician request whole blood units:	
	Permission to conduct the blood drive	
	1.	Notify Level II/III Commander, DCCS and Laboratory OIC/NCOIC that a physician is requesting whole blood for transfusion.
	2.	Once the Commander/DCCS grants permission, initiate the emergency whole blood collection. Trained medical personnel should oversee the process.
	Donor Recruitment	
	1.	!!!REMEMBER WHOLE BLOOD MUST BE TRANSFUSED TYPE SPECIFIC!!! Announce the whole blood drive. -First, donors should be recruited from the pre-screened donor pool, who's infectious disease testing results are negative or non-reactive. -If insufficient pre-screened donors are available, determine acceptability based on prospective donors: (1) are not fully suitable; (2) do not have a current screening and infectious disease testing history; (3) have no donation history.
	2.	Pull a pre screened donor list from TMDS: **Manage Donor**>**View Donor List**.
	3.	Select filters for ABO/Rh of the potential whole blood recipient, Screened (select **ALL**), Alert (select **ALL),** Cocom (select **CENTCOM**). Highlight your facility in the Available Facilities tab and click **Add**. Once your facility appears in the Search Facility box, click **Display Donor List**. The potential donor list for the blood type required will now appear on the screen.
	Donor and Testing Area Preparation	
	1.	Set up blood donor beds.
	2.	Perform QC on weighing device, (i.e., HemoFlow or Trip Scale). **NOTE:** If no trip scale is available, see section below Whole Blood Collection, Step 6.
	3.	Ensure counterweight is set at **585**g One milliliter of blood equals 1.053g 450 mL of Whole Blood equals 474g The final container must weigh 425g to 520g (405 to 495 ml) plus the weight of the primary blood bag with its anticoagulant. The target weight for a 450mL bag is 585g. • Under fill is less than 555g total weight • Over fill is greater than 650g total weight
	4.	Perform QC on the STAT Site M*, ABO/Rh Cards, HIV, HCV, HBsAg, Malaria, and RPR Kits.
	5.	Ensure the necessary equipment to perform donor screening, testing and collection are available. (See WBB Supply List (with NSNs)).

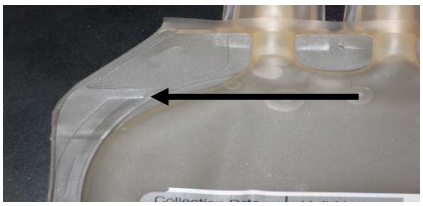
EMERGENCY WHOLE BLOOD COLLECTION SOP

	Perform Donor Screening		
	1.	**To the greatest extent possible, potential whole blood donors should be selected from among the pre-tested and qualified population documented in TMDS. This is the best practice to mitigate the risk of Transfusion Transmitted Disease (TTD) to the recipient.**	
	2.	Give donor Emergency Donation Record (Modified DD Form 572) and instruct donor to complete demographic information and to answer questionnaire by circling '**Y**'es or '**N**'o. If donor already has a pre-completed DD Form 572 on file, have them review the form and verify information is correct and update as necessary. While donor is completing **DD FORM 572**, screen for donor alerts and completed FDA test results in TMDS (deferrals).	
	3.	Locate donor's name on the Donor List displayed in TMDS. To the left of their name, click **View**. If all TTD results are Negative (within last 90 days) and there are no Donor Alerts, then the Donor is deemed fully **Pre- Screened/Tested.** To minimize risk to the recipient, it is recommended that pre-tested population be exhausted prior to resorting to collections from the untested population.	
	4.	A qualified interviewer will review Modified DD Form 572 for completeness and Donor Suitability Criteria following Steps 5-11 below (See attached Enclosures).using standards available for reference and download through Blood Portal at http://rceast.afghan.swa.army.mil/sites/tfmeda/ or at http://www.militaryblood.dod.mil/.	
	5.	**If**	**Then**
		There are all '**N**'o responses except for questions 22-24	Proceed to Step 6.
		There are any '**Y**'es responses except for questions 22-24	Document the reason for the 'Y'es response. Refer donor to a qualified provider to determine the donor's eligibility. Defer the donor as required, if necessary document "Ineligible" status on **DD FORM 572** and in TMDS.
		NOTE: For Q: 39, use State Tattoo and Permanent Make-up. Reference List (See Enclosure.) to screen for acceptability.	
	6.	Using the Direct Oral Questions (See Enclosure), ask the donor Group A, B, and C questions. Record name of interviewer on Modified DD Form 572.	
		If	**Then**
		The donor answers '**N**'o to each group.	Proceed to Step 7.
		The donor answers '**Y**'es to any group.	Defer donor for designated period of time and stop the donation process. Document donor as "Ineligible".

EMERGENCY WHOLE BLOOD COLLECTION SOP

	7.	Perform and record temperature on Modified DD Form 572. (See DD Form 572– Emergency Whole Blood Donation Record.)	
		If	**Then**
		≤99.5 ºF or 37.5 ºC	Proceed to Step 8.
		>99.5 ºF or 37.5 ºC	Stop the donation process. The donor is "Ineligible" at this time.
	8.	Perform and record measurements of donor pulse and blood pressure.	
		If	**Then**
		BP ≤ 180/100 and Pulse is ≤ 100 bpm	Proceed to Step 9.
		BP >180/100 and Pulse is > 100 bpm	Stop the donation process. The donor is "Ineligible" at this time.
	9.	For female donors, perform and record hematocrit/hemoglobin results on Modified DD Form 572, if possible. Male donors do not require hematocrit/hemoglobin testing.	
		If	**Then**
		≥38% or 12.5 g/dL	Proceed to Step 10.
		<38% or 12.5 g/dL	Defer donor and stop the donation process. The donor is "Ineligible" at this time.
	10.	Donor is physiologically acceptable to donate, have the donor sign the Modified DD Form 572 and proceed to Step 11.	
	11.	A competent medical authority should review the Modified DD Form 572 to determine the eligibility of the donor.	
		If	**Then**
		Acceptable	Donor is "Eligible". Proceed to Step 12.
		Unacceptable	Donor is "Ineligible". Stop donation process and document deferral as appropriate in TMDS.
	12.	Issue blood bag and test collection set to donor. Label bag and **DD FORM 572** with Whole Blood ISBT labels. Blood collection tubes (2 gold tops (SST), 2 pearl tops (PPT), 1 purple top tube) should be labeled with the corresponding small ISBT labels (without barcode). See Illustration to the left. If no labels are available, bags and all samples should be labeled with donor's full name and SSN or Blood Bag Segment Number.	

EMERGENCY WHOLE BLOOD COLLECTION SOP

	Whole Blood Collection	
	1.	Seat donor in blood donor table or reclining chair. Ask the donor their name and verify donor demographic information is correct on the Modified DD Form 572. Verify also that the labels the blood bag, sample tubes, and Modified DD Form 572 correctly correspond to each other and the donor. **NOTE:** If a discrepancy is noted, STOP and correct before proceeding further.
	2.	Ask donor if they are allergic to iodine or shellfish.
		If / **Then** Yes / Skip Step 3 and proceed to Step 4. No / Proceed to Step 3.
	3.	Utilizing Frepp-Sepp, apply Povidone Iodine (Frepp), 2% Aqueous Solution. Scrub vigorously for at least 30 seconds. Within a 3" diameter area around venipuncture site. Then Apply 10% Iodine (Sepp) to venipuncture site starting at the center and moving outward in concentric circles at least 1½ inches in all directions
	4.	For donors allergic to iodine follow the same procedure outlined above, but substitute a chlorohexidene scrub (ChloraPrep). **NOTE:** If a disinfectant is not available, clean the site with alcohol or other solution, if possible.
	5.	Allow area to dry.
	6.	Set-up trip scale (Manual or Electronic). Perform quality control, if possible, to obtain a counter-weight of 585 grams. **NOTE:** If no trip scale is available, the Terumo Single Blood Bag can be filled with whole blood to the mark pictured below. It is however recommended that weight then be checked with table top scale (if available)  The target weight for 450 mL is 585 grams. **Do not use if overfilled as blood clots may develop from an incorrect ratio of whole blood to anti-coagulant causing potential harm to the patient.**
	7.	Using a hemostat, clamp tubing between the needle and the main bag. This will prevent air contamination of blood after the needle cover is removed. Place tape within reach for anchoring the needle during phlebotomy. **NOTE:** Place a loose knot in the tubing approximately 6 inches from the needle **prior** to uncapping needle, if metal seal clips and hand crimpers are not available.
	8.	Apply tourniquet with enough pressure. If using a blood pressure cuff adjust to approximately 40-60 mm Hg.
	9.	Twist off the needle cover and inspect the needle for barbs or other defects.
	10.	Pull the skin taut below the venipuncture site.
	11.	With the bevel up, hold the needle at the hub, at approximately a 30-45 degree angle and pierce the skin with a smooth, quick thrust at the selected point of entry.

EMERGENCY WHOLE BLOOD COLLECTION SOP

	12.	When the bevel is completely under the skin, lower the angle of the needle to approximately 10º or less and, with a steady push, advance needle to penetrate the vein wall. Thread needle approximately ½ inch inside the vein to maintain a secure position and to lessen the chance of a clot forming.
	13.	Release the hemostat clamp on the collection bag tubing and observe the blood flow through the tubing and into the collection bag.
		If blood flow / **Then**
		Is impeded / Try adjusting the needle with least discomfort without hurting the donor.
		Is still impeded / Seek assistance from another phlebotomist before discontinuing the phlebotomy.
	14.	Fill sample tubes using the tube adaptor. After filling sample tubes, gently rock tubes to mix contents and verify once again that donation identification number on tubes corresponds to donation identification number on the collection bag and the **DD FORM 572**.
	15.	Instruct donor to relax their grip and to rhythmically squeeze every 5 to 10 seconds, relaxing between squeezes.
	16.	Secure the needle to the donor's arm with tape, across the hub or on the tubing near the hub of the needle. This will optimize the positioning of the needle to prevent rotation of the needle or drag on the tubing, which may impede blood flow. An additional piece of tape may be placed across the tubing lower on the arm.
	17.	Partially reduce the pressure by loosening the tourniquet or blood pressure cuff to approximately 20-40 mm Hg. **Mix blood bag several times during the collection to prevent clotting.**
	18.	Cover the phlebotomy site with sterile gauze dressing, to keep the site clean and needle out of view. Lift the gauze occasionally to monitor for a hematoma.
	19.	If a hematoma is evident, remove tourniquet and needle from donor's arm and place sterile gauze square over the hematoma and apply firm digital pressure while donor's arm is held above the heart level.
	20.	Record the following in the appropriate blocks on the DD Form 572: • Time phlebotomy was started • Initials of the phlebotomist
	21.	Watch for the signal of a filled unit by monitoring for the completion indicator of the weighing device or visual reference point (see step 6), if not using a weighing device. Record stop time on the **DD FORM 572**.
	22.	Seal the tubing 1 to 2 inches below the "Y" segment of the tubing using a metal seal slip and a hand crimper (or pulling tight the loose knot in the tubing).
	23.	Grasp the tubing on the donor side of the seal and press to remove a portion of blood in the tubing. Crimp the tubing at this spot. Cut the tubing between the two seals.
	24.	Remove tourniquet or blood pressure cuff and tape strips from donor's arm.
	25.	Place the fingers of one hand gently over the sterile gauze. DO NOT APPLY PRESSURE OVER THE NEEDLE. With the other hand, smoothly and quickly withdraw the needle. Apply firm pressure to the phlebotomy site.

EMERGENCY WHOLE BLOOD COLLECTION SOP

	26.	Instruct donor to apply firm pressure over the gauze. Encourage donor to maintain a relaxed elevated position, rather than tensing the muscle. This precaution will minimize the bleeding into the venipuncture area.
	27.	Discard the needle assembly into a sharps container.
	28.	Using a hand stripper/crimper, strip all blood from the tubing into the primary collection bag. This should be done ASAP after collection. (Stripping is pushing the blood in the tubing into the blood filled bag with the rollers on the stripper/crimper device)
	29.	Mix contents in the primary collection bag. DO NOT strip the tubing and allow tubing to refill without mixing. Release the stripper and allow the anti-coagulated blood to reenter the tubing. Perform this procedure three times.
	Processing Donor Units	
	1.	Take donor unit and donor sample tubes (2 gold tops (SST), 2 pearl tops (PPT), and 1 purple top tubes) to processing area.
	2.	Strip donor units segment tubing three times and mix, so as to avoid the development of clots.
	3.	Perform ABO, Rh type utilizing ABO/Rh Testing Card and purple top tube. Record results on Form 147.
	4.	Write the donor blood type **on the bag** (ABO/Rh Testing Card) along with date, time and phlebotomist initials of collection.
	5.	Write the expiration of the unit, which is 24 hours from collection if stored in a refrigerator (1 to 6 degrees Celsius) or 8 hours from collection if stored at room temperature (20 to 24 degrees Celsius).
	6.	Create product in TMDS while Rapid Testing is being performed. **NOTE: Rapid tests should be performed and found to be negative prior to transfusion, to the greatest extent possible. In situations requiring whole blood, available blood component inventory should continue to be transfused in lieu of whole blood until rapid testing has been performed and found to be negative.**
	Creating Whole Blood Units in TMDS	
	1.	From Manage Donation tab, select **Donate Product**.
	2.	Enter SSN of donor and click **Next**.
	3.	Verify demographic information for donor is correct, enter donation date and Donation ID number (from bar code label) and click **Add Products**.
	4.	Enter product code **E0009V00** for whole blood.
	5.	Enter expiration date (24 hours from collection if stored in a refrigerator (1 to 6 degrees Celsius) or 8 hours from collection if stored at room temperature (20 to 24 degrees Celsius).
	6.	Click **Add Product.**
	7.	Verify Donation ID/ ABO/Rh and expiration date then click **Next**.
	8.	Re-verify all demographic and unit data then click **Confirm Donation.**
	9.	Repeat steps 1-8 for each product collected.

EMERGENCY WHOLE BLOOD COLLECTION SOP

	Pre-Transfusion Rapid Testing	
	1.	**Rapid tests should be performed and found to be negative prior to transfusion, to the greatest extent possible. In situations requiring whole blood, available blood component inventory should continue to be transfused in lieu of whole blood until rapid testing has been performed and found to be negative.**
	2.	Spin down gold and pearl top tubes.
	3.	Perform rapid HBsAg, HCV, RPR using Serum/Plasma, and HIV, Malaria using whole blood. Testing should be performed IAW Test Kit package inserts and local SOP. Record reagent Name, Lot #, Exp Date, and Results on Form 145a.
	4.	Upon completion of rapid tests with negative results, whole blood unit may be issued for transfusion.
	5.	When time allows, rapid test results need to be entered into TMDS. To do this click on **Update Donation** under the Manage Donation tab.
	Issuing &Managing Whole Blood Inventory	
	1.	It is recommended that some sort of blood product issue document (ex., SF 518) be utilized to account for the issue of Whole Blood from the laboratory. WBB operations are at times chaotic and do not often allow for real-time updates of TMDS.
	2.	Provider requesting Fresh Whole Blood should sign Emergency Release Letter of understanding Form 150a or 150b as appropriate. Forms should be maintained in patient transfusion records.
	3.	Accurate dispositions of all Whole Blood units collected **MUST** be properly dispositioned in TMDS**.** Every unit must be created, transfused, expired or destroyed as appropriate.
	4.	**Fresh Whole Blood should be destroyed 24-hours post collection**. FWB can be stored at room temperature for 8-hours, and refrigerated thereafter.
	Processing Samples for Shipment & Testing	
	1.	Label aliquot (pour off) tubes with corresponding ISBT Labels ***with small*** **barcodes**. Position the ISBT label vertically toward top of tube as shown at left. **If ISBT labels are not available utilize the Donor SSN as the unit number.**
	2.	Pour 1 Pearl Top into 1 aliquot tube and mark as **Plasma**. Repeat for each Pearl Top tube. *3ml sample requirement per aliquot.
	3.	Pour contents of 2 Gold Top tubes into 1 aliquot tube and mark as **Serum**. * Do not fill over ¾ full to allow for expansion from freezing.
	4.	The seal of capped aliquot tubes should be reinforced with para-film wrap and placed into a biohazard shipping bag or rack. Repeat for each series.
	5.	Record sample and donor demographic data on Form 148 (Shipping Manifest). Include a printed copy of manifest with shipment and e-mail to BSD or designated facility, if possible.
	6.	Form 151- Whole Blood Transfusion Checklist must be submitted with shipment for **every unit of whole blood <u>transfused</u>**.
	7.	Copies of **DD FORM 572** and for all units of whole blood collected **MUST** be forwarded to BSD or designated facility with specimens and Form 145a.

EMERGENCY WHOLE BLOOD COLLECTION SOP

	8.	As soon as possible ship samples, Form 145a, Form 148, Form 151 and all **DD FORM 572**s in a blood box (Collins Blood Box) with ice bag(s) to your respective blood detachment. E-mail a copy of manifest to BSD or designated facility, if possible, or call to alert of incoming shipment. For Afghanistan: Blood Support Detachment TF MED/Bagram Airfield APO AE 09354 (BAF) 431-5446/5536 Blood Support Detachment Kandahar Air Field APO AE 09355 (KAF) 421-6171 Or **For other deployed units**, freeze samples until they can be shipped to a designated laboratory to perform FDA-approved testing.
	9.	The BSD or unit will send all samples for FDA approved testing in the rear enter results in TMDS and forward to submitting Role II or Role III upon completion. **NOTE: This results of this testing will be viewed as pre-screen for donors next donation.**
	10.	Any positive testing that is received will be forwarded to Preventive Medicine Consultant to ensure proper donor care and follow-up is initiated. At no time will laboratory staff notify donors directly regarding positive testing results.
References	AABB *Technical Manual*, current edition AABB *Standards for Blood Banks and Transfusion Services* JTTS Clinical Practice Guideline: Fresh Whole Blood (FWB) Transfusion Theater Medical Data Store (TMDS) Version 2.7.0.0 System User's Manual	
Enclosures	DD Form 572–Emergency Whole Blood Donation Record Direct Oral Questions Approved State Tattoo and Permanent Make-up List Acceptable Donor Worksheet Form 145A–Rapid Testing Worksheet Form 147–Eldon Card ABO/Rh Typing Record Form 148–Pre-Screen/Whole Blood Sample Shipping Manifest Form 150A–Emergency Release Letter of Understanding (tested) Form 150B–Emergency Release Letter of Understanding (un-tested) Form 151–Whole Blood Transfusion Checklist WBB Supply List (with NSNs)	

DD FORM 572–EMERGENCY WHOLE BLOOD DONATION RECORD

Please circle as appropriate:
WHOLE BLOOD DONATION
PRE-SCREEN

EMERGENCY WHOLE BLOOD DONATION RECORD
(Modified Version of the DD Form 572)

Blood Unit Number
Use Donor SSN if ISBT # Not Available

MTF/Location: _____ Donation Date: _____

Donor's Full Name: _____ Rank: _____ Branch: USA USAF USN USMC CIV

SSN: _____ Date of Birth (DDMMMYYYY): _____ Sex: M / F Ht/Wt: _____ (> 110 lbs) ABO/Rh (Blood Type) :_____

Deployed Unit/Location: _____ Local DSN Phone: _____ Local Cell/ Evening Phone_____

Redeployment Date: _____

Current Residence: Bldg/Tent # _____ RM # _____

Home Address (Stateside) _____

Home Phone Number: (_____) _____ Email: _____

Y 21. N	Female Donors: Are you pregnant now, or have you been Pregnant in the last 6 weeks?	Y 36. N	Have you ever had Chagas' disease, babesiosis, or Leishmaniasis?
Y 22. N	Are you feeling well and healthy today?	Y 37. N	In the past 12 months, have you been given a rabies shot?
Y 23. N	Have you read and do you understand all the donor information presented to you, and have all your questions been answered?	Y 38. N	In the past 12 months, have you had an accidental needle stick or come in contact with someone else's blood?
Y 24. N	Do you understand that if you are in a high risk group, you may have the AIDS virus and you can give it to someone else even though you may feel well and have a negative AIDS test?	Y 39. N	In the past 12 months, have you had a tattoo, ear or skin piercing, or acupuncture?
Y 25. N	Have you ever given blood under another name or Social Security Number?	Y 40. N	In the past 12 months, have you had close contact with a person with yellow jaundice or hepatitis or been given Hepatitis B Immune Globulin (HBIG)?
Y 26. N	In the past 8 weeks have you given blood, plasma or platelets?	Y 41. N	Have you ever had yellow jaundice, liver disease, hepatitis, or a positive test for hepatitis?
Y 27. N	Have you ever been refused as a blood donor or told not to donate blood?	Y 42. N	In the past 4 weeks, have you had any shots or vaccinations?
Y 28. N	In the past 12 months have you been under a doctor's care, had an illness, or surgery?	Y 43. N	In the past 8 weeks, have you received a smallpox vaccination or had close contact with the vaccination site of anyone else?
Y 29. N	In the past 12 months, have you received blood, blood products, or a tissue transplant including any you may have donated for yourself (autologous)?	Y 44. N	In the past month, have you taken Finasteride (Proscar, Propecia) or Isotretinoin (Accutane, Amnesteem, Claravis, Sotret) or in the past 6 months, have you taken Dutasteride (Avodart)
Y 30. N	In the past 3 years, have you had malaria?		
Y 31. N	In the past month, have you taken any pills or medications?		
Y 32. N	Have you ever been given growth hormone or received a dura mater (or brain covering) graft?		
Y 33. N	Have you ever taken Etretinate (Tegison) or Acitretin (Soriatane)?		
Y 34. N	Have you ever had cancer, a blood disease, or a bleeding problem?		
Y 35. N	Have you ever had chest pain, heart disease, or lung disease?		

(Use this section and reverse side of form to explain "Yes" answers above. With the exception of questions 22-24)

High Risk Oral Questions (10 Jan 2010) Asked By: _____ Donor: Temp: _____°F/°C (< 99.6°F/37.5°C) BP: _____/_____ (≤ 180/100) Pulse: _____ (< 100 bpm) HCT/Hgb: _____ (> 38% or 12.5 g/dL)

31. Medications: _____

Malaria Prophylaxis: Daily_____(Doxycycline) Weekly_____(Mefloquin) N/A _____

Your blood <u>will **NOT** be tested</u> for viral diseases prior to transfusion due to the emergency, if you any reason you feel your blood may not be safe or you could answer yes to the high risk questions, please do not donate today. I have read/ had explained to me the high risk questions and am not in a high risk category, and feel my blood is safe to donate at this time.

I verify that I have answered the questions honestly, and feel my blood is safe to be transfused. _____
Donor's Signature

Phlebotomist:_____ Start Time:_____ Stop Time:_____ (Should be < 15 minutes)

Bag Manufacturer _____Lot #:_____ Expiration date: _____ Segment Number: _____

The Modified DD Form 572 has been reviewed for completeness. If there are any risk factors that place the recipient at harm notify the ordering physician immediately for appropriate follow-up.

DD 572 (WB)
Version: 13 May 2010

DIRECT ORAL QUESTIONS

<table>
<tr><td>Preamble</td><td colspan="2">I am required to ask you some questions. If you do not understand a question, please ask me to explain it before answering. The reason for asking these questions is to determine your suitability as a volunteer blood donor. Your answers to these questions will be kept strictly confidential, but may result in you being asked not to donate blood, either temporarily or permanently. Do not respond until I have asked you the entire group of questions, which at that time only give me one answer – Yes or No.</td></tr>
<tr><td>Group A</td><td colspan="2">1. Do you have AIDS or have you ever had a positive test for the AIDS virus (HIV)?
2. Have you ever taken illegal drugs with a needle, even one time (including steroids)?
3. Have you ever taken clotting factor concentrates for a bleeding disorder such as hemophilia?
4. At any time since 1977, have you taken money or drugs in exchange for sex?
5. Male donors only: Have you had sex with another male, even one time since 1977?
A “Yes” answer to Group A is a PERMANENT DEFERRAL</td></tr>
<tr><td rowspan="11">Group B</td><td colspan="2">1. Were you born in, have you lived in, or traveled to any African country since 1977?</td></tr>
<tr><td>If response is</td><td>Then</td></tr>
<tr><td>No</td><td>Proceed to Group B, Question 3</td></tr>
<tr><td>Yes</td><td>Was it any of these countries: Cameroon, Benin, Central African Republic, Chad, Congo, Equatorial Guinea, Kenya, Gabon, Niger, Nigeria, Senegal, Togo or Zambia?</td></tr>
<tr><td>If No</td><td>Go to Group B, Question 3</td></tr>
<tr><td>If Yes – Travel Only</td><td>Proceed to Group B Question 2</td></tr>
<tr><td>If Yes – Born or Lived in</td><td>Document when, DEFER INDEFINITELY</td></tr>
<tr><td colspan="2">2. When you traveled to (name of country) did you receive a blood transfusion, or any other medical treatment with a product made from blood?</td></tr>
<tr><td>If response is</td><td>Then</td></tr>
<tr><td>No</td><td>Proceed to Group B, Question 3</td></tr>
<tr><td>Yes</td><td>DEFER INDEFINITELY</td></tr>
<tr><td colspan="2">3. Have you had sex with anyone who was born in, or has lived in any African Country since 1977?</td></tr>
<tr><td>If response is</td><td>Then</td></tr>
<tr><td>No</td><td>Proceed to Group C</td></tr>
<tr><td>Yes</td><td>Was it any of these countries: Cameroon, Benin, Central African Republic, Chad, Congo, Equatorial Guinea, Kenya, Gabon, Niger, Nigeria, Senegal, Togo or Zambia?</td></tr>
<tr><td>If No to listed countries</td><td>Proceed to Group C</td></tr>
<tr><td>Yes to listed countries</td><td>Document when, DEFER INDEFINITELY</td></tr>
</table>

Group C	1. Have you had sex in the last 12 months, even once, with anyone who has AIDS or has had a positive test for the AIDS virus? 2. Have you had sex in the last 12 months, even once, with anyone who has ever taken illegal drugs with a needle (including steroids)? 3. Have you had sex in the last 12 months, even once, with anyone who has taken clotting factor concentrates for a bleeding disorder such as hemophilia? 4. At any time in the last 12 months have you given money or drugs to someone to have sex with you? 5. At any time in the last 12 months, have you had sex with someone who has taken money or drugs in exchange for sex? 6. In the past 12 months, have you had a positive test for syphilis? 7. In the last 12 months have you had syphilis or gonorrhea or have you been treated for syphilis or gonorrhea? 8. In the last 12 months, have you received blood or blood products? 9. In the last 12 months, have you been incarcerated in a correctional institution (including jail or prison) for more than 72 consecutive hours? 10. In the last 12 months, have you taken (snorted) cocaine through your nose? 11. Female donors only: In the past 12 months, have you had sex with a man who had sex with another man, even one time since 1977? **A "Yes" answer to Group C is a TEMPORARY DEFERRAL for 12 months following the event**
Group D	1. Have you at any time since 1980 injected Bovine (Beef) Insulin? **A "Yes" answer to Group D is an INDEFINITE DEFERRAL**

APPROVED STATE TATTOO AND PERMANENT MAKE-UP LIST

Armed Services Blood Program
State Tattoo and Permanent Make-Up Reference List

NOTICE: The Department of Defense (DOD) assumes no risk for the use of this information by non-DoD personnel, blood programs, or individual medical institutions. The use of this information by DoD personnel is strictly for blood donor operations and must adhere to the current Service (Army, Navy and Air Force) specific Standard Operating Procedure dealing with the screening of blood donors.

NOTE: The following criteria provided by AABB Reference Standard 5.4.1A, Requirements for Allogeneic Donor Qualification, were used to determine acceptability of each state: (a) application by a state-regulated entity, (b) mandated use of sterile needles, (c) one-time use ink required.

If the state is acceptable, defer the donor for one week to ensure the site has properly healed. Although the state of application may be acceptable, prospective donors should be asked if the procedure was performed using sterile needles and single-use dye. If the donor answers no, or does not know, he/she should be deferred for 12 months. Prospective donors who had a procedure performed in a state listed as "No" must be deferred for 12 months from the time of application.

Armed Services Blood Program

State	Acceptable	Note
Alabama	YES	
Alaska	YES	
Arizona	YES	
Arkansas	YES	
California	NO	
Colorado	YES	
Connecticut	NO	
Delaware	YES	
District of Columbia	NO	
Florida	NO	

Revised Date: 14-Mar-12 BPL 12-01 BPL Date: 14-Mar-12 Page 1 of 3

Armed Services Blood Program

State	Acceptable	Note
Georgia	NO	
Hawaii	YES	
Idaho	NO	
Illinois	YES	
Indiana	YES	
Iowa	YES	
Kansas	YES	
Kentucky	YES	
Louisiana	YES	
Maine	YES	
Maryland	NO	
Massachusetts	NO	
Michigan	NO	
Minnesota	NO	
Mississippi	YES	
Missouri	YES	
Montana	YES	
Nebraska	YES	
Nevada	NO	
New Hampshire	NO	
New Jersey	YES	

Revised Date: 14-Mar-12 BPL 12-01 BPL Date: 14-Mar-12 Page 2 of 3

Armed Services Blood Program

State	Acceptable	Note
New Mexico	NO	
New York	NO	
North Carolina	YES	
North Dakota	NO	
Ohio	YES	
Oklahoma	NO	
Oregon	YES	
Pennsylvania	NO	
Rhode Island	YES	
South Carolina	YES	
South Dakota	YES	
Tennessee	YES	
Texas	YES	
Utah	NO	
Vermont	YES	
Virginia	YES	
Washington	YES	
West Virginia	YES	
Wisconsin	YES	
Wyoming	NO	

Revised Date: 14-Mar-12 BPL 12-01 BPL Date: 14-Mar-12 Page 3 of 3

ACCEPTABLE DONOR WORKSHEET

Document all results on **DD FORM 572**

Donor Weight	≥ 110 lbs
Donor Weight	≥ 110 lbs
Blood Pressure	≤ 180/100
Pulse	50-100 bpm (may be < 50 if donor is athletic)
Temperature	≤ 99.6°F
Hemoglobin	≥ 12.5 g/dL
Hematocrit	≥ 38 %
Medications	Do not collect from donors currently on antibiotics, to exclude anti-malarial prophylaxis. Donors taking medications that the competent medical authority deems may cause harm to the recipient must be deferred from donating. Be advised: If the purpose of the whole blood drive is derive a source of platelets for a patient then donors who have taken aspirin in the last 72 hours should be deferred.
Medical Conditions	Any donors with an underlying medical condition that could put them at risk if they were to donate should be deferred from donating i.e., heart and/or lung conditions.

FORM 145A–RAPID TESTING WORKSHEET

Rapid Testing Worksheet

Date of Testing:__________.

Tech:_______.

	Rapid Tests												RPR (ASI/Cardinal)		
													Rotator (100 +/- 5 rpm):		
	Malaria Now			HIV (Oraquick)			HCV (Oraquick)			HBsAg (CTK)			Needle Calibrated (0.5ml= 30 +/- 1 drop):		
	Lot #:			Lot #:			Lot #:			Lot #:			Lot #:		
Assigned Unit #	Exp:			Exp:			Exp:			Exp:			Exp:		
	Sample results		IQC OK?	Sample results		IQC OK?	Sample results		IQC OK?	Sample results		IQC OK?	"SR" Strong Reactive	"WR" Weak Reactive	"NR" Non-Reactive
POS EQC	R	NR		R	NR		R	NR		R	NR				
NEG EQC	R	NR		R	NR		R	NR		R	NR				
	R	NR		R	NR		R	NR		R	NR		SR	WR	NR
	R	NR		R	NR		R	NR		R	NR		SR	WR	NR
	R	NR		R	NR		R	NR		R	NR		SR	WR	NR
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	R	NR		R	NR		R	NR		R	NR		SR	WR	NR
	R	NR		R	NR		R	NR		R	NR		SR	WR	NR
	R	NR		R	NR		R	NR		R	NR		SR	WR	NR
	R	NR		R	NR		R	NR		R	NR		SR	WR	NR
	R	NR		R	NR		R	NR		R	NR		SR	WR	NR

√=Acceptable

R= Reactive

NR= Non-Reactive

Technical Review: _________ Date: _________

QA/QC Review: _________ Date: _________

Form 145a
V: 24 Nov 2010

FORM 147–ELDON CARD ABO/RH TYPING RECORD

Eldon Card ABO/Rh Typing

Date of Testing:__________.

	Eldon Card ABO/Rh Typing					
	Lot #					
	Exp:					Tech
Assigned Unit #	Anti-A	Anti-B	Anti-D	Rh Control	Interpretation	Initials
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		
	+ =	+ =	+ =	+ =		

Form 147
V: 28 June 2010

Technical Review: __________ Date: __________
QA/QC Review: __________ Date: __________

FORM 148–PRE-SCREEN/WHOLE BLOOD SAMPLE SHIPPING MANIFEST

Prescreen/Whole Blood Sample Shipping Manifest

Blood Unit Number				Donation Date	Donor Name		Branch of Service	Nationality	SSN or ID #	DOB	FOB/Base	Unit	Donation Type (PS or FWB)
Facility ID (W0138)	YR	Unit Id #	ABO RH		Last	First							

rm 148

FORM 150A–EMERGENCY RELEASE LETTER OF UNDERSTANDING (TESTED)

Provider Letter of Understanding for Emergency (Non-FDA) Whole Blood Units

I understand that Emergency Whole Blood Units are NOT FDA approved and transfusion of these units may result in unintended disease and/or transfusion reactions. I accept full responsibility for the units and the consequences that may follow transfusion.

Print Sign Date

_____ _____ _____

Provider

Form 150a

FORM 150B–EMERGENCY RELEASE LETTER OF UNDERSTANDING (UN-TESTED)

Provider Letter of Understanding for Untested Emergency Whole Blood Units

I understand that these Emergency Whole Blood Units have not had complete Rapid Testing prior to transfusion and transfusion of these units may result in an increased risk of unintended disease and/or transfusion reactions. I accept full responsibility for the units and the consequences that may follow transfusion.

Print Sign Date

_____ _____ _____

Provider

Form 150b

STANDARD FORM 518–BLOOD OR BLOOD COMPONENT RELEASE

518–123 NSN 7540–00–634–4158

MEDICAL RECORD | BLOOD OR BLOOD COMPONENT TRANSFUSION

SECTION I – REQUISITION

COMPONENT REQUESTED *(Check one)*
- ☐ RED BLOOD CELLS
- ☐ FRESH FROZEN PLASMA
- ☐ PLATELETS *(Pool of _____ units)*
- ☐ CRYOPRECIPITATE *(Pool of _____ units)*
- ☐ Rh IMMUNE GLOBULIN
- ☐ OTHER *(Specify)* _____

TYPE OF REQUEST *(Check ONLY if Red Blood Cell Products are requested.)*
- ☐ TYPE AND SCREEN
- ☐ CROSSMATCH

DATE REQUESTED

DATE AND HOUR REQUIRED

REQUESTING PHYSICIAN *(Print)*

DIAGNOSIS OR OPERATIVE PROCEDURE

I have collected a blood specimen on the below named patient, verified the name and ID No. of the patient and verified the specimen tube label to be correct.

VOLUME REQUESTED *(If applicable)* _____ ML

KNOWN ANTIBODY FORMATION/TRANSFUSION REACTION *(Specify)*

SIGNATURE OF VERIFIER

REMARKS:

IF PATIENT IS FEMALE, IS THERE HISTORY OF:

RhIG TREATMENT? DATE GIVEN: _____

HEMOLYTIC DISEASE OF NEWBORN? _____

DATE VERIFIED

TIME VERIFIED

SECTION II – PRE-TRANSFUSION TESTING

UNIT NO.	TRANSFUSION NO. / PATIENT NO.	TEST INTERPRETATION: ANTIBODY SCREEN	TEST INTERPRETATION: CROSSMATCH	PREVIOUS RECORD CHECK: ☐ RECORD ☐ NO RECORD / SIGNATURE OF PERSON PERFORMING TEST
DONOR	RECIPIENT	☐ CROSSMATCH NOT REQUIRED FOR THE COMPONENT REQUESTED		DATE
ABO	ABO	REMARKS:		
Rh	Rh			

SECTION III – RECORD OF TRANSFUSION

PRE-TRANSFUSION DATA

INSPECTED AND ISSUED BY *(Signature)*

AT *(Hour)* ON *(Date)*

IDENTIFICATION

I have examined the Blood Component container label and this form and I find all information identifying the container with the intended recipient matches item by item. The recipient is the same person named on this Blood Component Transfusion Form and on the patient identification tag.

1st VERIFIER *(Signature)*

2nd VERIFIER *(Signature)*

PRE-TRANSFUSION

TEMP. PULSE BP

DATE OF TRANSFUSION TIME STARTED

POST-TRANSFUSION DATA

AMOUNT GIVEN ML

TIME/DATE COMPLETED/INTERRUPTED

REACTION ☐ NONE ☐ SUSPECTED

TEMPERATURE PULSE BLOOD PRESSURE

If reaction is suspected—IMMEDIATELY:

1. Discontinue transfusion, treat shock if present, keep intravenous line open.
2. Notify Physician and Transfusion Service.
3. Follow Transfusion Reaction Procedures.
4. Do NOT discard unit. Return Blood Bag, Filter Set, and I.V. Solutions to the Blood Bank.

DESCRIPTION OF REACTION
- ☐ URTICARIA ☐ CHILL ☐ FEVER ☐ PAIN
- ☐ OTHER *(Specify)*

OTHER DIFFICULTIES *(Equipment, clots, etc.)*
- ☐ NO ☐ YES *(Specify)*

SIGNATURE OF PERSON NOTING ABOVE

PATIENT IDENTIFICATION—USE EMBOSSER (For typed or written entries give: Name—Last, first, middle; grade; rank; rate; hospital or medical facility)

SEX WARD

BLOOD OR BLOOD COMPONENT TRANSFUSION
Medical Record

STANDARD FORM 518 (REV. 9–92)
Prescribed by GSA/ICMR, FIRMR (41 CFR) 201–9.202–1

FORM 151–WHOLE BLOOD TRANSFUSION CHECKLIST

WHOLE BLOOD TRANSFUSION CHECKLIST

COMPLETE THIS CHECKLIST FOR EACH UNIT TRANSFUSED POST EVENT

LOCATION OF TRANSFUSION:	DATE:
WHOLE BLOOD UNIT #	

1. DONOR PRESCREENED FOR TRANSFUSION TRANSMITTED DISEASE (TTD) MARKERS WITH FDA APPROVED TESTS WITHIN LAST 90 DAYS?

YES_____ NO_____

2. DONORS SCREENED AT TIME OF COLLECTION USING RAPID TESTS FOR:

MALARIA YES_____ NO_____
HIV YES_____ NO_____
HBV YES_____ NO_____
HCV YES_____ NO_____
RPR YES_____ NO_____

3. RAPID TEST RESULTS AVAILABLE PRIOR TO PRODUCT RELEASE?

YES_____ NO_____

4. DONORS SCREENED USING **DD572** & CURRENT SOP ? YES_____ NO_____

5. BLOOD TUBES COLLECTED AT THE TIME OF COLLECTION FOR FOLLOW UP WITH FDA TTD TESTING YES_____ NO_____

6. INTERNATIONAL SOCIETY FOR BLOOD TRANSFUSION (ISBT) LABELS USED YES_____ NO_____

7. TUBES AND A COPY OF **DD572** FORWARDED TO BSD? YES_____ NO_____

8. UNIT ACCOUNTED FOR IN TMDS? YES_____ NO_____

9. WAS COMPONENT THERAPY AVAILABLE WHEN FWB WAS GIVEN YES_____NO_____

10. PLEASE PROVIDE ANY INFLUENCING FACTORS THAT PREVENTED YOU FROM FOLLOWING THE SOP FOR THIS TRANSFUSION EVENT (IF APPLICABLE):

_____

_____

_____

_____

INDIVIDUAL COMPLETING CHECKLIST

Print Name	**Signature**

This checklist is to be kept on file for a minimum of one (1) year. Forward a copy to BSD with corresponding samples for Every unit of Whole Blood transfused.

Form 151

WBB SUPPLY LIST (WITH NSNS)

Item Description	Stock# / NSN #
SHARPS Container	6515014922824
Biohazard Bags	0707A950012
Leak Resistant Chucks	3583001093
Gloves-SM	4352MG6001
-MED	4352484802
-LRG	4352MG6003
Surgical Tape	6510009268882
Sphygmomanometer	3596994215
Stethoscope	3596994510
Tempa Dots	4509005122
Lancet	F50924058510
Alcohol Pads	4725APP104
2x2 Gauze	3583001806
STAT SiteM	1750SB900900
STAT SiteM Test Cards	6550015096101
Blood Bag Scales-Hemo Flow	6515015137010
Blood Bag Stand	6515004114375
Terumo Single Blood Bags	6515014802307
Frepp/Sepp Kit	4335260288
4x4 Gauze	3583002634
Hand Stripper/Sealer/Cutter	6515011405267
Hand Sealer Clips	06814R4418
Scissors	6515003650640
Hemostats	5867097442
Adapter MS DIR 100S Luer 100S	723364902
Purple Top (EDTA Plasma)	0723367861
Pearl Top (PPT)	0723362788
Gold Top (SST)	723364902
Coban 5x1	4509001583
Eldon Card (Rapid ABO/Rh)	65500 8T003314
HIV 1/2 RA OraQuick	6550015267424
ORAQUIK HCV	6550015899845
ONSITE (CTK) HBSAG (Hep B)	6550008T000102
Malarial Rapid Test	6550081332341
RPR Test Kit	6550015110291

APPENDIX C

ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGs

Purpose. The purpose of this Appendix is to ensure an understanding of DoD policy and practice regarding inclusion in CPGs of "off-label" uses of U.S. Food and Drug Administration (FDA)–approved products. This applies to off-label uses with patients who are armed forces members.

Background. Unapproved (i.e., "off-label") uses of FDA-approved products are extremely common in American medicine and are usually not subject to any special regulations. However, under Federal law, in some circumstances, unapproved uses of approved drugs are subject to FDA regulations governing "investigational new drugs." These circumstances include such uses as part of clinical trials, and in the military context, command required, unapproved uses. Some command requested unapproved uses may also be subject to special regulations.

Additional Information Regarding Off-Label Uses in CPGs. The inclusion in CPGs of off-label uses is not a clinical trial, nor is it a command request or requirement. Further, it does not imply that the Military Health System requires that use by DoD health care practitioners or considers it to be the "standard of care." Rather, the inclusion in CPGs of off-label uses is to inform the clinical judgment of the responsible health care practitioner by providing information regarding potential risks and benefits of treatment alternatives. The decision is for the clinical judgment of the responsible health care practitioner within the practitioner-patient relationship.

Additional Procedures.

1. Balanced Discussion. Consistent with this purpose, CPG discussions of off-label uses specifically state that they are uses not approved by the FDA. Further, such discussions are balanced in the presentation of appropriate clinical study data, including any such data that suggest caution in the use of the product and specifically including any FDA-issued warnings.
2. Quality Assurance Monitoring. With respect to such off-label uses, DoD procedure is to maintain a regular system of quality assurance monitoring of outcomes and known potential adverse events. For this reason, the importance of accurate clinical records is underscored.
3. Information to Patients. Good clinical practice includes the provision of appropriate information to patients. Each CPG discussing an unusual off-label use will address the issue of information to patients. When practicable, consideration will be given to including in an appendix an appropriate information sheet for distribution to patients, whether before or after use of the product. Information to patients should address in plain language: a) that the use is not approved by the FDA; b) the reasons why a DoD health care practitioner would decide to use the product for this purpose; and c) the potential risks associated with such use.