	FRESH WHOLE BLOOD (FWB) TRANSFUSION				
Original Release/Approval Oct 2006		Oct 2006	Note: This CPG requires an annual review.		
Reviewed:	Jun 2012	Approved:	17 Jul 2012		
Supersedes: Fresh Whole Blood (FWB) Transfusion, updated 19 Nov 08			ansfusion, updated 19 Nov 08		
Minor Cl	Minor Changes (or) Changes are substantial and require a thorough reading of this CPG (or)				
Significa	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, <u>Blood Donor Pre-Screening SOP</u>).

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.

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 typespecific. There are risks associated with the use of FWB, including but not limited to increased risk of transmitted blood-borne diseases (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 >4000 FWB transfusions to U.S. personnel during OIF/OEF have resulted in one Hepatitis C (HCV) and Human T-Lymphocyte Virus (HTLV) seroconversion. 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., RBCs, PLTs, Cryo, FFP), or when stored components transfused in large volumes 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 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.
 - 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, <u>Blood Donor Pre-Screening SOP</u>). FWB should be collection for transfusion as outlined in Appendix B, <u>Emergency Whole Blood Drive SOP</u>.
 - 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, <u>Emergency Whole Blood Drive SOP</u> 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 blood-borne disease transmission (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, <u>WBB</u> <u>Supply List (with NSNs)</u>).
- 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 AJBPO. 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, <u>Blood Donor Pre-Screening SOP</u> and Appendix B, <u>Emergency</u> <u>Whole Blood Drive SOP</u>.

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 recalling 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).
- 1. **Procedure**. See Appendix B for <u>DD Form 572–Emergency Whole Blood Donation</u> <u>Record</u>.

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.

Fresh Whole Blood (FWB) Transfusion

- b. Performance/Adherence Measures.
 - 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.

- Massive transfusion in trauma patients: tissue hemoglobin oxygen saturation predicts poor outcome. Moore FA, Nelson T, McKinley BA, Moore EE, Nathens AB, Rhee P, Puyana JC, Beilman GJ, Cohn SM; StO2 Study Group. J Trauma. 2008 Apr;64(4):1010-23.
- ^{2.} Repine TB, Perkins JG, Kauvar DS, Blackborne L. The use of fresh whole blood in massive transfusion. *J Trauma*. 2006;60:S59-S69.
- ^{3.} 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.
- ^{4.} CENTCOM FRAGO 09-1222: Joint Theater Blood Program Update: 4 May 2007.
- ^{5.} *Emergency War Surgery*, 2004, Third US Revision, Chap 7: Shock and Resuscitation.
- ^{6.} Theater MTF-specific Standard Operating Procedures (SOPs).
- ^{7.} Technical Manual, AABB, Bethesda Maryland, 16th Edition, 2008.
- ^{8.} Standards for Blood Banks & Transfusion Services, AABB, 25th Ed, February 2008.
- ^{9.} Theater Medical Data Stores (TMDS), Blood Portal, Standard Operating Procedures (<u>http://militaryblood.dod.mil/Staff/eMOAS.aspx</u>).

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.

	BLOOD DONOR PRE-SCREENING SOP
Materials and	Use the following materials and equipment as applicable.
Equipment	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 <u>Enclosures-Blood Donor Pre-Screening SOP</u>.)
	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.

APPENDIX A BLOOD DONOR PRE-SCREENING SOP

	BLOOD DONOR PRE-SCREENI	NG SOP			
Cond	lucting the Pre-Screening Event				
1	Medical History-Provide prospective dono demographic info is legible and as complete				
2	Interview -Trained medical personnel will a donate based on the information collected – on the Blood Portal at: <u>http://rceast.afghar</u>	-Donor eligibility requirements. can found			
	If	Then			
	There are all ' N 'o responses except for questions 22-24	Proceed to Step 4.			
	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 Per <u>Tattoo and Make-up Reference List</u>) to scree				
3	Using the Direct Oral Questions, ask the donor Group A, B, and C questions. Record name of interviewer on DD Form 572. See <u>Enclosures-Blood Donor Pre-Screening</u> <u>SOP</u> .				
	If	Then			
	The donor answers 'N'o to each group	Proceed to Step 5.			
	The donor answers ' Y 'es to any group	Defer donor for designated period of time and stop the donation process. Document donor as "Ineligible".			
Regi	ster Donor in TMDS per Manage Donations/Donors SOP (#4). See steps below.				
-	id Infectious Disease Testing. rformed, see Emergency Whole Blood Collection SOP for instructions.				
Perf	orm 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 F	Enclosures-Blood Donor Pre-Screening SOP.				

BLOOD DONOR PRE-SCREENING SOP

Proc	essing 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 <i>with small</i> 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 ³ / ₄ 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. Maintain the (pre-screening) DD FORM 572s 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 	
7		
	For Afghanistan:Blood Support DetachmentBlood Support DetachmentTF MED/Bagram AirfieldKandahar Air FieldAPO AE 09354APO AE 09355(BAF) 431-5446/5536(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

	Main	tain 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	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.			
		ES: 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.			
	1	REMEMBER WHOLE BLOOD MUST BE TRANSFUSED TYPE SPECIFIC!!!			
References	2. 3.	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 F	Form 572–Emergency Whole Blood Donation Record			
	Appr	oved State Tattoo and Permanent and Make-up Reference List			
	Direc	et Oral Questions			
	Form	147–Eldon Card ABO/Rh Typing Record			
	Form	148-Pre-Screen/Whole Blood Sample Shipping Manifest			

Guideline Only/Not a Substitute for Clinical Judgment July 2012

Fresh Whole Blood (FWB) Transfusion

Please circle as appropriate:						
WHOLE BLOOD DONATION						
PRE-SCREEN	EMERGENCY WHOLE (Modified Ver	BLOOD D		Blood Unit Number		
MTF/Location:	Donation Date:			Use Donor SSN if ISBT # Not Available		
	Rank:					
SCN- Data	of Birth (DDMMMYYYY):	Sar M/F H	ABO/Rh (Blood)	Tumo) -		
	Local DSN Phon		(> 110 lbs)	-)r-)·		
Redeployment Date:						
Current Residence: Bldg/Tent # Home Address (Stateside)	RM #					
Home Phone Number: ()	Email:					
Y 21. N Female Donors: Are w	ou pregnant now, or have you been	Y 36. N	Have you ever had Chagas' disease	a babasiosis, or		
Pregnant in the last 6 v	veeks?		Leishmaniasis?			
Y 22. N Are you feeling well at		Y 37. N				
	you understand all the donor information	Y 38. N	In the past 12 months, have you ha			
	ave all your questions been answered?		come in contact with someone else			
	Y 24. N Do you understand that if you are in a high risk group, you may Y 39. N In the past 12 months, have you had a tattoo, ear or skin piercing,					
	ad you can give it to someone else even		or acupuncture?			
Y 26. N In the past 8 weeks have	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					
Y 27. N Have you ever been re	fased as a blood donor or told not to	Y 42. N	positive test for hepatitis? In the past 4 weeks, have you had a	any shots or vaccinations?		
	nave you been under a doctor's care, had	Y 43. N	In the past 8 weeks, have you receip			
an illness, or surgery? V 20 N is the mart 12 membr	have you received blood, blood products,	V 44 N	had close contact with the vaccinat In the past month, have you taken I			
or a tissue transplant in	cluding any you may have donated for	1 1. 4	or Isotretinoin (Accutane, Amneste	em, Claravis, Sotret) or in the		
yourself (autologous)?			past 6 months, have you taken Dut	asteride (Avodart)		
Y 30. N In the past 3 years, hav						
	e you taken any pills or medications? ven growth hormone or received a dura (g) graft?					
Y 33. N Have you ever taken E (Soriatane)?	tretinate (Tegison) or Acitretin					
Y 34. N Have you ever had can problem?	cer, a blood disease, or a bleeding					
Y 35. N Have you ever had che	st pain, heart disease, or hing disease?					
(Use this section and reverse side of for	n to explain "Yes" answers above. With ti	he exception of que	stions 22-24)			
High Risk Oral Onestions (10 Jan 2010) Asked By: Do	nor Term	*F/*C BP: / Pulse:	HCT/Hzb:		
 Medications: 		(= 99.6°F/37.		100 bpm) (> 38% or 12.5 g/dL)		
JI. menodulis:						
Malaria Prophylaxis: Daily <u>(</u> Dox	rcycline) Weekly(Mefloquin) N	//A				
	l diseases prior to transfusion due to the e onate today. I have read/had explained to					
I verify that I have answered the question	ms honestly, and feel my blood is safe to b	e transfused.	Donor's Signatur	a		
Phlobotomist:			(Should be < 15 minutes)			
Bag Manufacturer	Lot #:	Exp	iration date:	Segment Number:		
The Modified DD Form 572 has been r appropriate follow-up.	eviewed for completeness. If there are an	y risk factors that p	lace the recipient at harm notify the	ordering physician immediately for		
DD 572 (WB) Version: 13 May 2010						

DD FORM 572-EMERGENCY WHOLE BLOOD DONATION RECORD

		es Blood Program
State I		Permanent Make-Up
NOTION The Desert		ence List
by non-DoD personne information by DoD p	el, blood programs, o ersonnel is strictly fo /, Navy and Air Force	D) assumes no risk for the use of this information or individual medical institutions. The use of this or blood donor operations and must adhere to the e) specific Standard Operating Procedure dealing
Allogeneic Donor Qua	alification, were used	AABB Reference Standard 5.4.1A, Requirements for I to determine acceptability of each state: (a) mandated use of sterile needles, (c) one-time use
Although the state of the procedure was pe no, or does not know,	application may be a rformed using sterile , he/she should be de	for one week to ensure the site has properly healed. acceptable, prospective donors should be asked if e needles and single-use dye. If the donor answers eferred for 12 months. Prospective donors who had "No" must be deferred for 12 months from the time
	Armed Serv	vices Blood Program
State	Armed Serv Acceptable	vices Blood Program Note
		•
State Alabama Alaska	Acceptable	•
Alabama	Acceptable YES	•
Alabama Alaska Arizona	Acceptable YES YES	•
Alabama Alaska Arizona Arkansas	Acceptable YES YES YES	•
Alabama Alaska Arizona Arkansas Califomia	Acceptable YES YES YES YES	•
Alabama Alaska Arizona Arkansas California Colorado	Acceptable YES YES YES YES NO	•
Alabama Alaska	Acceptable YES YES YES YES NO YES	•
Alabama Alaska Arizona Arkansas California Colorado Connecticut	Acceptable YES YES YES YES NO YES NO	•

APPROVED STATE TATTOO AND PERMANENT AND MAKE-UP REFERENCE LIST

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

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

Preamble	to explain it before answering. T suitability as a volunteer blood confidential, but may result in y	uestions. If you do not understand a question, please ask me The reason for asking these questions is to determine your donor. Your answers to these questions will be kept strictly ou being asked not to donate blood, either temporarily or til I have asked you the entire group of questions, which at yer – Yes or No.			
Group A	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				
Group B	1. Were you born in, have you lived in, or traveled to any African country since 1977?				
	If response is	Then			
	No	Proceed to Group B, Question 3			
	Yes	Was it any of these countries: Cameroon, Benin, Central African Republic, Chad, Congo, Equatorial Guinea, Kenya, Gabon, Niger, Nigeria, Senegal, Togo or Zambia?			
	If No	Go to Group B, Question 3			
	If Yes – Travel Only	Proceed to Group B Question 2			
	If Yes – Born or Lived in	Document when, DEFER INDEFINITELY			
	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?				
	If response is	Then			
	No	Proceed to Group B, Question 3			
	Yes	DEFER INDEFINITELY			
	3. Have you had sex with anyone who was born in, or has lived in any African Country since 1977?				
		ne who was born in, or has lived in any African Country since			
		ne who was born in, or has lived in any African Country since Then			
	1977?				
	1977? If response is	Then			
	1977? If response is No	Then Proceed to Group C Was it any of these countries: Cameroon, Benin, Central African Republic, Chad, Congo, Equatorial Guinea, Kenya,			

	A "Yes" answer to Group D is an INDEFINITE DEFERRAL
Group D	1. Have you at any time since 1980 injected Bovine (Beef) Insulin?
	A "Yes" answer to Group C is a TEMPORARY DEFERRAL for 12 months following the event
	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?
	10. In the last 12 months, have you taken (snorted) cocaine through your nose?
	9. In the last 12 months, have you been incarcerated in a correctional institution (including jail or prison) for more than 72 consecutive hours?
	8. In the last 12 months, have you received blood or blood products?
	7. In the last 12 months have you had syphilis or gonorrhea or have you been treated for syphilis or gonorrhea?
	6. In the past 12 months, have you had a positive test for syphilis?
	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?
	4. At any time in the last 12 months have you given money or drugs to someone to have sex with you?
	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?
	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)?
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?

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			
	+ =	+ =	+ =	+ =					
	+ =	+ =	+ =	+ =					
	+ =	+ =	+ =	+ =					
	+ =	+ =	+ =	+ =					
	+ =	+ =	+ =	+ =					
	+ =	+ =	+ =	+ =					
	+ =	+ =	+ =	+ =					
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	+ =	+ =	+ =	+ =					
	+ =	+ =	+ =	+ =					
	+ =	+ =	+ =	+ =					
	+ =	+ =	+ =	+ =					
	+ =	+ =	+ =	+ =					
	+ =	+ =	+ =	+ =					
	+ =	+ =	+ =	+ =					
	+ =	+ =	+ =	+ =					
Form 147 Technical Review: Date: V: 28 June 2010 QA/QC Review: Date:									

FORM 147-ELDON CARD ABO/RH TYPING RECORD

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

Prescreen/Whole Blood Sample Shipping Manifest

Blood U	Init N	lumber	2. 14 9.2.5		Donor Na	ame							Donation
Facility ID (W0138)	YR	Unit ld #	ABO RH	Donation Date	Last	First	Branch of Service	Nationality	SSN or ID #	DOB	FOB/Base	Unit	Donation Type (PS or FWB)
	\square												
													
. г.													
<u> </u>	-												

Form 148 V. May 2012

Materials and	Use the following materials and equipment as applicable:
Equipment	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 (of other 1001 field globilometer) 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 <u>Enclosures-Emergency Whole Blood</u> <u>Collection SOP</u> . Theater Medical Data Store (TMDS), Blood Portal.

APPENDIX B EMERGENCY WHOLE BLOOD COLLECTION SOP

F	1	EMERGENCY WHOLE BLOOD COLLECTION SOP				
Quality Control	Perfo	orm QC on STAT Site M (or equivalent POCT Hemaglobinometer)				
	Perfo	orm QC on ABO/Rh Testing Card, RPR, HCV, HBsAg, HIV, and Malaria Kits				
		instrument package inserts and local SOPs for procedures.)				
	Medical personnel should be trained by BSD or other qualified personnel.					
Procedure	Perfo	orm 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.				
	Done	or 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) <u>plus</u> 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 <u>WBB Supply List (with NSNs)</u>).				

	EMERGENCI WHOLE DLOOD COLLECTION SOI					
Per	form Donor Screening					
1	from among the pre-tested and qu	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	to complete demographic information 'N'o. If donor already has a pre-com- form and verify information is correct	ecord (Modified DD Form 572) and instruct donor on and to answer questionnaire by circling ' Y 'es or npleted DD Form 572 on file, have them review the ect and update as necessary. While donor is for donor alerts and completed FDA test results in				
3	click View . If all TTD results are N Donor Alerts, then the Donor is dee	List displayed in TMDS. To the left of their name, egative (within last 90 days) and there are no med fully Pre- Screened/Tested. To minimize risk that pre-tested population be exhausted prior to ested population.				
4	Donor Suitability Criteria following standards available for reference and	Modified DD Form 572 for completeness and 5 Steps 5-11 below (See attached Enclosures).using d download through Blood Portal at tes/tfmeda/ or at http://militaryblood.org				
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				
7	Perform and record temperature on Emergency Whole Blood Donation	Modified DD Form 572. (See <u>DD Form 572–</u> <u>Record</u> .)			
	If	Then			
	≤99.5 °F or 37.5 °C	Proceed to Step 8.			
	>99.5 °F or 37.5 °C	Stop the donation process. The donor is "Ineligible" at this time.			
8	Perform and record measurements of	of donor pulse and blood pressure.			
	If	Then			
	$BP \le 180/100$ 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 rec Form 572, if possible.	ord hematocrit/hemoglobin results on Modified DD			
	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 s and DD FORM 572 with Whole Bl collection tubes (2 gold tops (SST), purple top tube) should be labeled v small ISBT labels (without barcode left. If no labels are available, bags be labeled with donor's full name at Segment Number.	ood ISBT labels. Blood2 pearl tops (PPT), 1with the corresponding). See Illustration to theand all samples should			

Who	le 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 iod	ine or shellfish.			
	If	Then			
	Yes	Skip Step 3 and proceed to Step 4.			
	No	Proceed to Step 3.			
3	vigorously for at least 30 seconds. Within a 3" diameter area around ve	ne Iodine (Frepp), 2% Aqueous Solution. Scrub enipuncture site. Then Apply 10% Iodine (Sepp) to ter and moving outward in concentric circles at			
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	a counter-weight of 585 grams. NOTE: If no trip scale is available,	nic). Perform quality control, if possible, to obtain the Terumo Single Blood Bag can be filled with clow. It is however recommended that weight then vailable)			
		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 press approximately 40-60 mm Hg.	ure. If using a blood pressure cuff adjust to			
9	Twist off the needle cover and inspe	ect the needle for barbs or other defects.			
10	Pull the skin taut below the venipun	cture 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 DLOOD	eelletteiteel			
	12	When the bevel is completely under the skin, lower the angle of the needle to approximately 10° or less and, with a steady push, advance needle to penetrate th wall. Thread needle approximately ½ inch inside the vein to maintain a secure por 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	to mix contents and verify once agai	ptor. After filling sample tubes, gently rock tubes n that donation identification number on tubes on number on the collection bag and the DD			
	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 3), 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		f the seal and press to remove a portion of blood is spot. Cut the tubing between the two seals.			
	24	Remove tourniquet or blood pressur	e cuff and tape strips from donor's arm.			
	over the sterile gauze. DO NOT APPLY With the other hand, smoothly and quickly essure to the phlebotomy site.					

 	EMERGENCY WHOLE DLOOD COLLECTION SOF
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.
Proc	essing 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.
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.
Crea	ting 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 (24hrs post collection)
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.

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.					
Issui	ng &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.					
Proc	essing Samples for Shipment & Testing					
1	Label aliquot (pour off) tubes with corresponding ISBT Labels <i>with small</i> 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 ³ / ₄ 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.					

		EMERGENCI WHOLE BLOOD COL					
	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 sample laboratory to perform FDA-approved test	es until they can be shipped to a designated ting.				
	9	The BSD or unit will send all samples for results in TMDS and forward to submitting					
		NOTE: This results of this testing will donation.	be viewed as pre-screen for donors next				
	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	AAB	BB Technical Manual, current edition					
	AAB	B Standards for Blood Banks and Transfus	sion Services				
	JTTS	S Clinical Practice Guideline: Fresh Whole	Blood (FWB) Transfusion				
	Thea	ater Medical Data Store (TMDS) Version 2.7.0.0 System User's Manual					
Enclosures	DD I	Form 572–Emergency Whole Blood Donati	ion Record				
	Direc	ct Oral Questions					
	App	Approved State Tattoo and Permanent Make-up List					
	Acce	ptable Donor Worksheet					
	Form	145a-Rapid Testing Worksheet					
	Form	Form 147–Eldon Card ABO/Rh Typing Record					
	Form	n 148–Pre-Screen/Whole Blood Sample Shi	ipping Manifest				
	Form	1 150a – Emergency Release Letter of Unde	rstanding (tested)				
	Form	1 150b- Emergency Release Letter of Unde	erstanding (un-tested)				
	Form	151–Whole Blood Transfusion Checklist					
	WBI	3 Supply List (with NSNs)					

There airels a supervisitor]	
Please circle as appropriate:		
WHOLE BLOOD DONATION	EVERCENCY WHOLE BLOOD DONATION RECORD	
PRE-SCREEN	EMERGENCY WHOLE BLOOD DONATION RECORD (Modified Version of the DD Form 572)	Blood Unit Number
	(Atomined Version of the DD Form 5/2)	
MTF/Location:	Donation Date:	Use Donor SSN if ISBT # Not Available
Donor's Full Name:	Rank: Branch: USA USAF USN USMC CIV	
SSN: Date	of Birth (DDMMMYYYY): Sex: M / F Ht/Wt: ABO/Rh (Blood	d Type) :
	(> 110 lbs)	
Deployed Unit/Location: Redeployment Date:	Local DSN Phone: Local Cell/ Evening Phone	
	RM #	
Home Address (Stateside)		
Home Phone Number: ()	Email:	
V 21 N Equals Denors: Are y	ou pregnant now, or have you been Y 36. N Have you ever had Chagas' disea	na babariaria ar
Pregnant in the last 6 v	weeks? Leichmaniasis?	
Y 22. N Are you feeling well a		been given a rabies shot?
	you understand all the donor information Y 38. N In the past 12 months, have you 1 have all your questions been answered? come in contact with someone el	
	at if you are in a high risk group, you may Y 39. N In the past 12 months, have you I	
have the AIDS virus at	nd you can give it to someone else even or acupuncture?	
though you may feel u Y 25. N Have you ever given b	well and have a negative AIDS test? blood under another name or Social Y 40. N In the past 12 months, have you b	and close contract with a new re-
Y 25. N Have you ever given b Security Number?	blood under another name or Social Y 40. N in the past 12 months, have you i with yellow jaundice or hepatitis	
-	Immune Globulin (HBIG)?	<u> </u>
Y 26. N In the past 8 weeks have	we you given blood, plasma or platelets? Y 41. N Have you ever had yellow jaundi	ce, liver disease, hepatitis, or a
Y 27. N Have you ever been re	positive test for hepatitis? afused as a blood donor or told not to Y 42. N In the past 4 weeks, have you had	any shots or vaccinations?
donate blood?		
		eived a smallpox vaccination or
X 29 N In the past 12 months	have you received blood, blood products, Y 44. N In the past month, have you taken	
	ncluding any you may have donated for or Isotretinoin (Accutane, Amnes	steem, Claravis, Sotret) or in the
yourself (autologous)?	past 6 months, have you taken De	atasteride (Avodart)
Y 30. N In the past 3 years, hav	ve you had malana?	
Y 31. N In the past month, have		
1 52. N riste you ever been gr mater (or brain coverin	iven growth hormone or received a dura ng) graff?	
Y 33. N Have you ever taken E		
(Soriatane)?		
Y 34. N Have you ever had can problem?	ncer, a blood disease, or a bleeding	
	est pain, heart disease, or lung disease?	
1 55. N Have you ever had che	est pain, neart disease, or ning disease?	
(Use this section and reverse side of for	m to explain "Yes" answers above. With the exception of questions 22-24)	
T 1 T 1 0 10		
High Kisk Oral Questions (10 Jan 2010	0) Asked By: Donor: Temp:^F/*C BP:/ Pulse (< 99.6*F/37.5*C) (< 180/100) (*	
31. Medications:		(- 100 opin) (- 50% of 12.5 gont)
JI. Multandis.	<u>_</u>	
Malaria Prophylaxis: Daily (Dox	ycycline) Weekly (Mefloquin) N/A	
Your blood will NOT be texted for vir	al diseases prior to transfusion due to the emergency, if you any reason you feel your blood may	not be each or your could answer use to
	ai diseases prior to transmision due to the emergency, if you any reason you real your oscold may ionate today. I have read/ had explained to me the high risk questions and am not in a high risk (
donate at this time.		
	ons honestly, and feel my blood is safe to be transfused.	
I verify that I have answered the question		10
I verify that I have answered the question	Donor's Signate	
	ř.	
Phiebotomist:	Start Time: Stop Time: (Should be < 15 minutes)	
	Start Time: Stop Time: (Should be < 15 minutes)	
Phiebotomist:	Start Time: Stop Time: (Should be < 15 minutes)	
Phlebotomist: Bag Manufacturer The Modified DD Form 572 has been r	Start Time: Stop Time: (Should be < 15 minutes)	Segment Number:
Phlebotomist: Bag Manufacturer	Start Time:Stop Time:(Should be < 15 minutes) Lot #:Expiration date:	Segment Number:
Phlebotomist: Bag Manufacturer The Modified DD Form 572 has been r appropriate follow-up.	Start Time:Stop Time:(Should be < 15 minutes) Lot #:Expiration date:	Segment Number:
Phlebotomist: Bag Manufacturer The Modified DD Form 572 has been r appropriate follow-up. DD 572 (WB)	Start Time:Stop Time:(Should be < 15 minutes) Lot #:Expiration date:	Segment Number:
Phlebotomist: Bag Manufacturer The Modified DD Form 572 has been r appropriate follow-up.	Start Time:Stop Time:(Should be < 15 minutes) Lot #:Expiration date:	Segment Number:
Phlebotomist: Bag Manufacturer The Modified DD Form 572 has been r appropriate follow-up. DD 572 (WB)	Start Time:Stop Time:(Should be < 15 minutes) Lot #:Expiration date:	Segment Number:

DD FORM 572-EMERGENCY WHOLE BLOOD DONATION RECORD

Preamble	to explain it before answering. T suitability as a volunteer blood confidential, but may result in y	uestions. If you do not understand a question, please ask me The reason for asking these questions is to determine your donor. Your answers to these questions will be kept strictly ou being asked not to donate blood, either temporarily or til I have asked you the entire group of questions, which at yer – Yes or No.
Group A	1. Do you have AIDS or have y	you ever had a positive test for the AIDS virus (HIV)?
	2. Have you ever taken illegal of	trugs with a needle, even one time (including steroids)?
	3. Have you ever taken clotting hemophilia?	factor concentrates for a bleeding disorder such as
	4. At any time since 1977, have	e 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
Group B	1. Were you born in, have you	lived in, or traveled to any African country since 1977?
	If response is	Then
	No	Proceed to Group B, Question 3
	Yes	Was it any of these countries: Cameroon, Benin, Central African Republic, Chad, Congo, Equatorial Guinea, Kenya, Gabon, Niger, Nigeria, Senegal, Togo or Zambia?
	If No	Go to Group B, Question 3
	If Yes – Travel Only	Proceed to Group B Question 2
	If Yes – Born or Lived in	Document when, DEFER INDEFINITELY
	2. When you traveled to (name medical treatment with a pro	of country) did you receive a blood transfusion, or any other duct made from blood?
	If response is	Then
	No	Proceed to Group B, Question 3
	Yes	DEFER INDEFINITELY
	3. Have you had sex with anyou 1977?	ne who was born in, or has lived in any African Country since
	1977?	ne who was born in, or has lived in any African Country since
	1977? If response is	ne who was born in, or has lived in any African Country since Then
	1977? If response is No	Then Proceed to Group C Was it any of these countries: Cameroon, Benin, Central African Republic, Chad, Congo, Equatorial Guinea, Kenya,

Group D	 Have you at any time since 1980 injected Bovine (Beef) Insulin? A "Yes" answer to Group D is an INDEFINITE DEFERRAL
Group D	the event
	A "Yes" answer to Group C is a TEMPORARY DEFERRAL for 12 months following
	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?
	10. In the last 12 months, have you taken (snorted) cocaine through your nose?
	9. In the last 12 months, have you been incarcerated in a correctional institution (including jail or prison) for more than 72 consecutive hours?
	8. In the last 12 months, have you received blood or blood products?
	7. In the last 12 months have you had syphilis or gonorrhea or have you been treated for syphilis or gonorrhea?
	6. In the past 12 months, have you had a positive test for syphilis?
	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?
	4. At any time in the last 12 months have you given money or drugs to someone to have sex with you?
	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?
	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)?
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?

State T		es Blood Program Permanent Make-Up
State		ence List
by non-DoD personne information by DoD p current Service (Army with the screening of NOTE: The following	ment of Defense (DOI el, blood programs, o ersonnel is strictly fo , Navy and Air Force blood donors. criteria provided by A	D) assumes no risk for the use of this information or individual medical institutions. The use of this or blood donor operations and must adhere to the e) specific Standard Operating Procedure dealing AABB Reference Standard 5.4.1A, Requirements for to determine acceptability of each state: (a)
Although the state of the procedure was pe	application may be a rformed using sterile	for one week to ensure the site has properly healed. acceptable, prospective donors should be asked if e needles and single-use dye. If the donor answers eferred for 12 months. Prospective donors who had
		"No" must be deferred for 12 months from the time
a procedure performe	d in a state listed as	
a procedure performe of application.	d in a state listed as	"No" must be deferred for 12 months from the time
a procedure performe of application. State	d in a state listed as Armed Serv	"No" must be deferred for 12 months from the time rices Blood Program
a procedure performe	d in a state listed as Armed Serv Acceptable	"No" must be deferred for 12 months from the time rices Blood Program
a procedure performe of application. State Alabama	Armed Serv Acceptable YES	"No" must be deferred for 12 months from the time rices Blood Program
a procedure performe of application. State Alabama Alaska	Armed Serv Acceptable YES YES	"No" must be deferred for 12 months from the time rices Blood Program
a procedure performe of application. State Alabama Alaska Arizona Arkansas	Armed Serv Acceptable YES YES	"No" must be deferred for 12 months from the time rices Blood Program
a procedure performe of application. State Alabama Alaska Arizona	Armed Serv Acceptable YES YES YES YES	"No" must be deferred for 12 months from the time rices Blood Program
a procedure performe of application. State Alabama Alaska Arizona Arkansas Califomia	Armed Serv Acceptable YES YES YES YES YES NO	"No" must be deferred for 12 months from the time rices Blood Program
a procedure performe of application. State Alabama Alaska Arizona Arkansas California Colorado	Armed Serv Acceptable YES YES YES YES NO YES	"No" must be deferred for 12 months from the time rices Blood Program
a procedure performe of application. State Alabama Alaska Arizona Arkansas California Colorado Connecticut	Armed Serv Acceptable YES YES YES YES NO YES NO YES	"No" must be deferred for 12 months from the time rices Blood Program

APPROVED STATE TATTOO AND PERMANENT MAKE-UP LIST

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

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-1	2 BPL 12-01	BPL Date: 14-Mar-12	Page 3 of 3

ACCEPTABLE DONOR WORKSHEET

Document all results on DD FORM 572

	I
Donor Weight	\geq 110 lbs
Donor Weight	\geq 110 lbs
Blood Pressure	$\leq 180/100$
Pulse	50-100 bpm (may be < 50 if donor is athletic)
Temperature	\leq 99.6°F
Hemoglobin	\geq 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



		on Card A		yping 		\$	
	Lot #	Eldon	Card ABO/	Rh Typing			
	Exp:					Tech	
Assigned Unit #	Anti-A	Anti-B	Anti-D	Rh Control	Interpretation	Initials	
	+ =	+ =	+ =	+ =			
	+ =	+ =	+ =	+ =			
	+ =	+ =	+ =	+ =			
	+ =	+ =	+ =	+ =			
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147 June 2010			Tech Q/	nical Revie	w:	Date:	

FORM 147-ELDON CARD ABO/RH TYPING RECORD

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

Prescreen/Whole Blood Sample Shipping Manifest

Blood U	Init N	lumber		South States	Donor Na	ame							Donation
Facility ID (W0138)	YR	Unit Id #	ABO RH	Donation Date	Last	First	Branch of Service	Nationality	SSN or ID #	DOB	FOB/Base	Unit	Type (PS or FWB)
. e													
	\square												
<u> </u>													

Form 148 V. May 2012 FORM 150A- EMERGENCY RELEASE LETTER OF UNDERSTANDING (TESTED)

	<u>Units</u> hat Emergency Whole proved and transfusio	
reactions. I ac	unintended disease an cept full responsibility nces that may follow t	y for the units and
Print	Sign	Date

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

<u>Provider Letter of Understanding</u> for <u>Untested Emergency Whole Blood Units</u>

I understand that these Emergency Whole Blood Units <u>have not had complete Rapid Testing prior to</u> <u>transfusion</u> 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		

MEDICAL RECORD	BLOOD OR BLOOD COMPONENT TRANSFUSION										
		SECTION I -	REQUISITION								
COMPONENT REQUESTED (CI	neck one)	TYPE OF REQUEST (Check Products are requested.)	TYPE OF REQUEST (Check ONLY if Red Blood Cell REQUESTING PHYSICIAN (Print)		rint)						
RED BLOOD CELLS		i roducio are roquestea.y									
FRESH FROZEN PLASMA		TYPE AND SCREEN		DIAGNOSIS OR OPERATIVE PROCEDURE							
PLATELETS (Pool of units)		CROSSMATCH									
CRYOPRECIPITATE (Pool of units) Rh IMMUNE GLOBULIN		DATE REQUESTED DATE AND HOUR REQUIRED		I have collected a blood specimen on the belor named patient, verified the name and ID No. of th patient and verified the specimen tube label to b							
						OTHER (Specify)	ashlat			correct.	
						VOLUME REQUESTED (If applicable)ML.		KNOWN ANTIBODY FORMATION/TRANSFUSION REACTION (Specify)		SIGNATURE OF VERIFIER	
REMARKS:		IF PATIENT IS FEMALE, IS T	HERE HISTORY OF:	DATE VERIFIED							
		RhIG TREATMENT? DATE G	VEN:								
		HEMOLYTIC DISEASE OF N	EWBORN?	TIME VERIFIED							
		SECTION II - PRE-TR	ANSFUSION TESTING	1							
UNIT NO.	TRANSFUSION NO.	TEST INTE	RPRETATION	PREVIOUS RECORD CHECK:							
	DITIENT NO	ANTIBODY SCREEN	CROSSMATCH		NO RECORD						
	PATIENT NO.			SIGNATURE OF PERSON PER	RFORMING TEST						
DONOR	RECIPIENT	-									
			QUIRED FOR THE COMPONEN	T REQUESTED	DATE						
ABO	ABO	REMARKS:									
Rh	Rh										
		SECTION III - RECO	RD OF TRANSFUSION								
	PRE-TRANSFUSION DATA		AMOUNT GIVEN	POST-TRANSFUSION DATA TIME/DATE COMPLETED/IN							
NSPECTED AND ISSUED BY (Signature)			ML	TIME/ DATE COMPLETED/IN	TERROP TED						
			REACTION	TEMPERATURE PULSE	BLOOD PRESSURE						
AT (Hour) IDENTIFICATION	ON (Date)										
have examined the Blood	Component container label a	and this form and I find all	If reaction is suspected—IMMEDIATELY: 1. Discontinue transfusion, treat shock if present, keep intravenous line open.								
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.		 Notify Physician and Transfusion Service. Follow Transfusion Reaction Procedures. Do NOT discard unit. Return Blood Bag, Filter Set, and I.V. Solutions to the Blood Bani 									
1st VERIFIER (Signature)			DESCRIPTION OF REACTION								
			URTICARIA CHILL FEVER PAIN								
	2nd VERIFIER (Signature)										
2nd VERIFIER (Signature)											
2nd VERIFIER (Signature)				The second se							
			OTHER DIFFICULTIES (Equip								
PRE-TRANSFUSION	PULSE	RP	NO YES (Spe	ecify)							
	PULSE TIME STARTED	BP		ecify)							
PRE-TRANSFUSION TEMP. DATE OF TRANSFUSION	TIME STARTED EMBOSSER (For typed or writ	BP ten entries give: Name—Last,	NO YES (Special Signature of Person No	ecify)	WARD						
PRE-TRANSFUSION TEMP. DATE OF TRANSFUSION	TIME STARTED		NO YES (Special Signature of Person No	ncify) TING ABOVE	WARD						
PRE-TRANSFUSION TEMP. DATE OF TRANSFUSION	TIME STARTED EMBOSSER (For typed or writ		NO YES (Special Signature of Person No	ncify) TING ABOVE	WARD						
PRE-TRANSFUSION TEMP. DATE OF TRANSFUSION	TIME STARTED EMBOSSER (For typed or writ		NO YES (Special Signature of Person No	nerfy) TING ABOVE SEX							
PRE-TRANSFUSION TEMP. DATE OF TRANSFUSION	TIME STARTED EMBOSSER (For typed or writ		NO YES (Special Signature of Person No	Northy) SEX BLOOD OR BLOOD COM							
PRE-TRANSFUSION TEMP. DATE OF TRANSFUSION	TIME STARTED EMBOSSER (For typed or writ		NO YES (Special Signature of Person No	SEX BLOOD OR BLOOD CON Medice STANDARD FORM 5	MPONENT TRANSFUSION						
PRE-TRANSFUSION TEMP. DATE OF TRANSFUSION	TIME STARTED EMBOSSER (For typed or writ		NO YES (Special Signature of Person No	SEX BLOOD OR BLOOD CON Medice STANDARD FORM 5	MPONENT TRANSFUSION						

STANDARD FORM 518-BLOOD OR BLOOD COMPONENT RELEASE

FORM 151–WHOLE BLOOD TRANSFUSION CHECKLIST

COMPLETE THIS CHECKLIST FOR EACH UNIT TRANSF	USED POST EVENT	
LOCATION OF TRANSFUSION:	DATE:	
WHOLE BLOOD UNIT #		
1. DONOR PRESCREENED FOR TRANSFUSION TRANSMITTED DISEASE (TTD) MARKERS WITH FDA APPROVED TESTS WITHIN LAS		
	YES	NO
2. DONORS SCREENED AT TIME OF COLLECTION USING RAPID TES	TS 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 PREVENT FOLLOWING THE SOP FOR THIS TRANSFUSION EVENT (IF APPLICA)		
INDIVIDUAL COMPLETING CHECKLI	ST	
Print Name	Signature	
This checklist is to be kept on file for a minimum of one (1) ye to BSD with corresponding samples for <u>Every</u> unit of Whole 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)	6550015871889 (individual card)		
	6550015119294 (25 ct multi-test kit)		
HIV 1/2 RA OraQuick	6550015267424		
ORAQUIK HCV	6550015899845		
ONSITE (CTK) HBSAG (Hep B)	6550008T000102		
Malarial Rapid Test	6550081332341		
RPR Test Kit	6550015110291		

WBB SUPPLY LIST (WITH NSNS)

APPENDIX C

ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGs

- **1. 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.
- 2. 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.
- **3.** Additional Information Regarding Off-Label Uses in CPGs. The inclusion in CPGs of offlabel 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-patient relationship.

4. Additional Procedures.

- a. 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.
- b. 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.
- c. 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.