

FRESH WHOLE BLOOD (FWB) TRANSFUSION

Original Release/Approval	Sep 2014	Note: This CPG requires an annual review.
Reviewed:	N/A	Approved for PACOM: DEC 2014
Supersedes:	Fresh Whole Blood (FWB) Transfusion, updated 17 Jul 2012	

- 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 hypofibrinogenemia.) 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

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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.

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- 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).

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- 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 or other communications network. If using TMDS follow this path: >Manage Donor>View Donor List, Select filters for ABO/Rh of the potential whole blood recipient, Screened (select **ALL**), Alert (select **ALL**), COCOM (select USPACOM). 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.
- 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).

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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) DoD Trauma Registry (DoDTR)
- 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, Blackburne 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.

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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 USPACOM JTTS Director,
JTS Director and USPACOM SG**

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

Blood Donor Pre-Screening SOP

Materials and Equipment	<p>Use the following materials and equipment as applicable.</p> <ul style="list-style-type: none"> • Modified DD Form 572s • Clip Boards • Gloves • Testing Collection Set: premade bags with 2x2 gauze, 2 gold tops (SST), 2 pearl tops (PPT) and 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	<ul style="list-style-type: none"> • Modified DD FORM 572, Form 147, Form 148 (See Enclosures—Blood Donor Pre-Screening SOP.) • Theater Medial Data Store (TMDS), Blood Portal 	
Quality Control	<p>Perform QC on ABO/Rh Testing Card (See instrument package inserts for procedures). Medical personnel should be trained by BSD or other qualified personnel.</p>	
Procedure	<p>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 Role 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.</p> <p>Perform the following steps when Pre-screening Donors:</p>	
	<p>Prepare for Donor Pre-Screening Event</p>	
	<table border="1" style="width: 100%;"> <tr> <td style="width: 5%; text-align: center;">1.</td> <td>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.</td> </tr> </table>	1.
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.	

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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.	<p>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: https://www.militaryblood.dod.mil/default.aspx (CAC enabled) >Blood Operations>Blood Program Letters. Download the following documents: AABB Medication List DHQ v.1.3 ASBP Medication List Supplement V.2 Blood Donor Immunizations List</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #e0e0e0;"> <th style="width: 50%; text-align: center;">If</th> <th style="width: 50%; text-align: center;">Then</th> </tr> </thead> <tbody> <tr> <td>There are all ‘N’o responses except for question 1.</td> <td>Proceed to Step 3.</td> </tr> <tr> <td>There are any ‘Y’es responses except for question 1.</td> <td>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 all donors that answer yes to questions 2-6, 10 -20 and 22-35. See notes below for guidance on specific questions. Defer the donor as required, if necessary document “Ineligible” status on DD FORM 572 and in TMDS.</td> </tr> </tbody> </table> <p>NOTES: For Q: 4, use AABB Medication List and ASBP Medication List Supplement from ASBPO website (See step 2) to screen for acceptability. For Q: 7, refer to TMDS or Donation Records for last donation date and consult with qualified provider. For Q: 8, refer to Blood Donor Immunization list from ASBPO website (See step 2). For Q: 9, See Donor Acceptability Flowchart to determine donor’s eligibility. For Q: 21, use State Tattoo and Permanent Make-up Reference List. See Tattoo and Make-up Reference List to screen for acceptability. For Q:36, Refer donor to a qualified provider to determine the donor’s eligibility. For Q: 37: Document the name of the Prophylaxis and accept Donor.</p>	If	Then	There are all ‘N’o responses except for question 1.	Proceed to Step 3.	There are any ‘Y’es responses except for question 1.	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 all donors that answer yes to questions 2-6, 10 -20 and 22-35. See notes below for guidance on specific questions. Defer the donor as required, if necessary document “Ineligible” status on DD FORM 572 and in TMDS.
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3.	Phlebotomy - Collect 1 Purple Top, 2 Pearl Top (PPT), 2 Gold Top (SST) and label with small Pre-Screen (500 number series) ISBT labels (<i>without</i> 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).						

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	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 .

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Processing Samples for Shipment & Testing	
1.	Centrifuge Gold Top and Pearl Top Tubes for 5 minutes at 4000 RPM.
2.	<p>Label aliquot (pour off) tubes with corresponding ISBT Labels <i>with small barcodes</i>. 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.</p> 
3.	Pour 1 Pearl Top into 1 aliquot tube and mark as Plasma . Repeat for each Pearl Top tube. *3ml sample requirement per aliquot. Do not fill over ¾ full to allow for expansion from freezing.
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.	<p>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. See USPACOM Key Military Blood Program Directory</p> <p>If shipment is delayed. Freeze samples until they can be shipped to a designated laboratory to perform FDA-approved testing.</p>
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 Role II or Role 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.

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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.
<p>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.</p> <p style="text-align: center;">!!!REMEMBER WHOLE BLOOD MUST BE TRANSFUSED TYPE SPECIFIC!!!</p>	
References	<ol style="list-style-type: none"> 1. AABB <i>Technical Manual</i>, current edition 2. AABB <i>Standards for Blood Banks and Transfusion Services</i> 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

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Enclosures	DD Form 572-Emergency Whole Blood Donation Record Approved State Tattoo and Permanent and Make-up Reference List Form 147-Eldon Card ABO/Rh Typing Record Form 148-Pre-Screen/Whole Blood Sample Shipping Manifest USPACOM Key Military Blood Program Directory Donor Acceptability Flow Chart for Question 9
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DD FORM 572—EMERGENCY WHOLE BLOOD DONATION RECORD

Please circle as appropriate:

**WHOLE BLOOD DONATION
PRE-SCREEN**

EMERGENCY WHOLE BLOOD DONATION RECORD (Modified 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: _____ Sex: M/F Weight: _____ ABO/Rh (Blood Type): _____
 (DDMMM/YYYY) (> 110 lbs)
 Deployed Unit/Location: _____ Local DSN Phone: _____ Local Cell/ Evening Phone _____
 Redeployment Date: _____
 Current Residence: Bldg/Tent # _____ RM # _____
 Home Address (Stateside) _____
 Home Phone Number: (____) _____ Email: _____

- | | |
|---|---|
| <p>Y 1. N Are you feeling healthy and well today?
 Y 2. N Are you currently taking an antibiotic?
 Y 3. N Are you currently taking any other medication for an infection?
 Y 4. N Please read the Medication Deferral List. Are you now taking or have you ever taken any medications on the Medication Deferral List?
 Y 5. N In the past 48 hours have you taken aspirin or anything that has aspirin in it?
 Y 6. N In the past 6 weeks, Female donors: have you been pregnant or are you pregnant now?
 Y 7. N In the past 16 weeks have you donated blood, platelets or plasma?
 Y 8. N In the past 8 weeks have you had any vaccinations or other shots?
 Y 9. N In the past 8 weeks have you had contact with someone who had a smallpox vaccination?
 IN THE PAST 12 MONTHS HAVE YOU
 Y 10. N Had a blood transfusion?
 Y 11. N Had a transplant such as organ, tissue, or bone marrow?
 Y 12. N Had a graft such as bone or skin?
 Y 13. N Come into contact with someone else's blood?
 Y 14. N Had an accidental needle-stick exposing you to someone else's blood and/or body fluid?
 Y 15. N Had sexual contact with anyone who has HIV/AIDS or has had a positive test for the HIV/AIDS virus?
 Y 16. N Had sexual contact with a prostitute or anyone else who takes money or drugs or other payment for sex?
 Y 17. N Had sexual contact with anyone who has ever used needles to take drugs or steroids, or anything NOT prescribed by their doctor?
 Y 18. N Had sexual contact with anyone who has hemophilia or has used clotting factor concentrates?
 Y 19. N Female donors: Had sexual contact with a male who has ever had sexual contact with another male?
 Y 20. N Had sexual contact or lived with a person who has Hepatitis
 Y 21. N Had a tattoo or ear/body piercing?
 Y 22. N Had or been treated for syphilis or gonorrhea?
 Y 23. N Been in juvenile detention, lockup, jail, or prison for more than 72 hours?</p> | <p>Y 24. N FROM 1977 TO THE PRESENT, HAVE YOU
 Received money, drugs, or other payment for sex?
 Y 25. N Male donors: had sexual contact with another male, even once?
 HAVE YOU EVER
 Y 26. N Had a positive test for the HIV/AIDS virus?
 Y 27. N Used needles to take drugs, steroids, or anything NOT prescribed by your doctor?
 Y 28. N Used clotting factor concentrates?
 Y 29. N Had Hepatitis after 11th Birthday?
 Y 30. N Had Malaria, Chagas disease, or Babesiosis?
 Y 31. N Received a dura mater (or brain covering) graft?
 Y 32. N Had any type of cancer, including leukemia?
 Y 33. N Had any problems with your heart or lungs?
 Y 34. N Had a bleeding condition or a blood disease?
 Y 35. N Have any of your relatives had Creutzfeldt-Jakob disease?
 Y 36. N In the past 12 months, have you been under a doctor's care for an illness or surgery?
 Y 37. N Are you currently taking malaria prophylaxis if required?</p> |
|---|---|

(Use this section and reverse side of form to explain "Yes" answers above. With the exception of question 1.)

Medications: _____ Donor: Temp: _____ °F/°C BP: _____ / _____ Pulse: _____ HCT/Hgb: _____
 (= 99.6°F/37.5°C) (≤ 180/100) (≤ 100 bpm) (≥ 38% or 12.5 g/dL)

Your blood **will NOT be tested** for viral diseases prior to transfusion due to the emergency. If for any reason you feel your blood may not be safe, please do not donate today.

I 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: _____

Reviewer: _____ Date: _____ TMDS/TBLD entered by: _____ (initials)/ _____ (Date)

This Modified DD Form 572 is to be used only in a deployed/contingency environment for collection of emergency whole blood.

DD 572 (WB)
Version: 28 August 2014

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) applied by a state-regulated entity, (b) with sterile needles, (c) and ink that has not been reused. 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 ink that has not been reused. 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	YES	

Joint Theater Trauma System Clinical Practice Guideline

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	YES	
Mississippi	YES	
Missouri	YES	
Montana	YES	
Nebraska	YES	
Nevada	NO	
New Hampshire	NO	
New Jersey	YES	

Revised Date: 24-Oct-13

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BPL Date 30-Oct-13

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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	

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US PACOM KEY MILITARY BLOOD PROGRAM DIRECTORY

KEY MILITARY BLOOD PROGRAM DIRECTORY

HQ U.S. PACIFIC COMMAND
JOINT BLOOD PROGRAM OFFICE
Commander, HQ USPACOM
Attn: Code J0717
PO Box 64045
Camp HM Smith, HI 96861-4045
DSN: 315-477-7895
COM: (808) 477-7895
FAX: (808) 477-7895
Secure: (808) 477-7895
Cell 904-535-1201
LT Frederick Matheu
Frederick.matheu@pacom.mil
SIPR: Frederick.matheu@pacom.smil.mil

HAWAII
AREA JOINT BLOOD PROGRAM
Commander
Tripler, Army Medical Center
1 Jarrett White Road
TAMC, HI 96859-5000
DSN: 315-433-5304
COM: (808) 433-5304/6779
FAX: (808) 433-6912

OKINAWA
AREA JOINT BLOOD PROGRAM
Commanding Officer
U.S. Naval Hospital, Okinawa
Armed Services Blood Bank Center
PSC 482 Box 1620
FPO AP 96362
DSN: 643-7737
COM: 011-81-98-970-5555,
after tone dial 643-7737

JAPAN AREA JOINT PROGRAM
Commanding Officer
U.S. Naval Hospital Yokosuka
FPO AP 96350-1620
DSN: 243-8573/8561
COM: 011-81-468-16-8573/8561
FAX: 243-8564
Secure: 243-7630

GUAM AREA JOINT BLOOD PROGRAM
Commanding Officer
U.S. Naval Hospital Guam
FPO AP 96538-1600
DSN: (315) 344-9753/9433
COM: 671-344-9753/9433
FAX: 671-344-9252
Secure: 344-9295 (CO)
344-9289 (POMI)

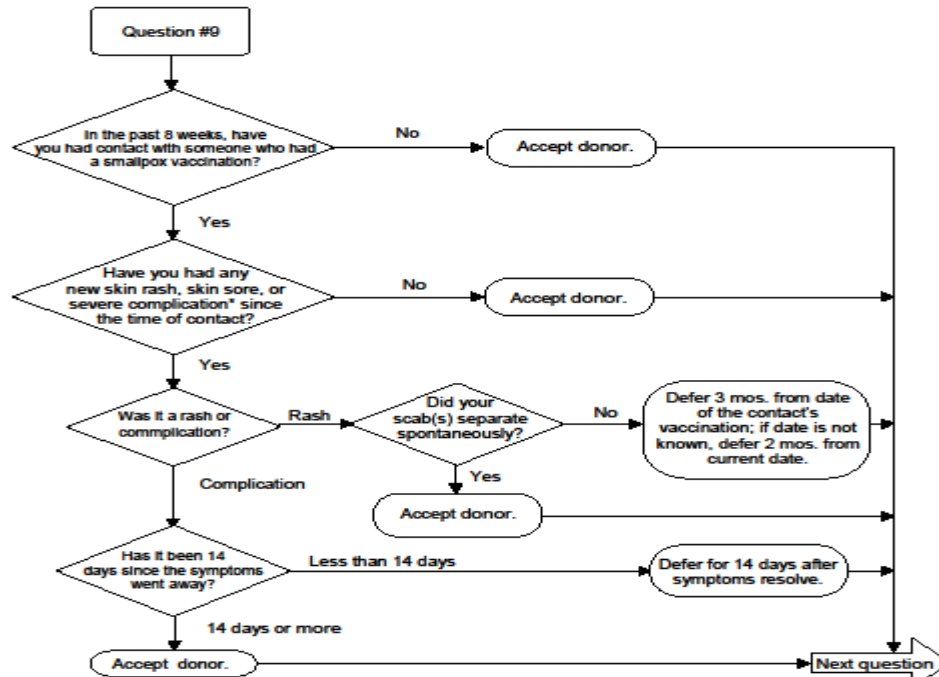
KOREA
AREA JOINT BLOOD PROGRAM
Commander, 95TH BSD
UNIT 15479
APO AP 96271-5479
DSN: (315) 753-3597/3635
COM: 011-82-31-690-3597/3635

ALASKA AREA JOINT BLOOD PROGRAM
Commander
U.S. Air Force 673rd Medical Group
5955 Zeamer Ave
Elmendorf, AK 99506-3700
DSN: 317-580-6540
COM: 907-580-6571
FAX: 317-580-6556

Donor Acceptability Flow Chart for Question 9

Question: 9. In the past 8 weeks, have you had contact with someone who had a smallpox vaccination?

Donor Eligibility: Certain vaccinations may contain live infectious agents. A donor who has had close contact with the vaccination site, bandages covering the vaccination site or materials that might have come into contact with an unbandaged vaccination site, including clothing, may be exposed to the live infectious agents and should not be a donor for a specified period of time.



*Severe complications include the following: rash (resembling blisters) covering a small or large area of the body; necrosis (tissue death) in the area of exposure; encephalitis (inflammation of the brain); infection of the cornea (eye); and localized or systemic skin reaction in someone with eczema or other chronic skin condition.

Joint Theater Trauma System Clinical Practice Guideline

APPENDIX B EMERGENCY WHOLE BLOOD COLLECTION SOP

Materials and Equipment	<p>Use the following materials and equipment as applicable:</p> <ul style="list-style-type: none"> • 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) <p>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.</p> <ul style="list-style-type: none"> • Blood Trip Scale with 585±2g trip counter-weight and QC weights or HemoFlow. • Testing Collection Set: premade bags with 2x2 gauze, 2 gold tops (SST), 2 pearl tops (PPT), 1 purple top tube and 1 plain red top tube (more tubes may be required if using short draw or small volume tubes) • ChloroPrep, 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	<p>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.</p>

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EMERGENCY WHOLE BLOOD COLLECTION SOP

Quality Control	<p>Perform QC on STAT Site M (or equivalent POCT Hemaglobinometer)</p> <p>Perform QC on ABO/Rh Testing Card, RPR, HCV, HBsAg, HIV, and Malaria Kits (See instrument package inserts and local SOPs for procedures.)</p> <p>Medical personnel should be trained by BSD or other qualified personnel.</p>
Procedure	Perform the following steps when the physician request whole blood units:
	Permission to conduct the blood drive
	1. Notify Role 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, whose 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 USPACOM). 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 585g 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. <u>The target weight for a 450mL bag is 585g.</u> <ul style="list-style-type: none"> • 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)).	

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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 the Modified DD 572 to determine if the donor is eligible to donate based on the information collected and Donor Suitability Criteria following Steps 5-11 below –Donor eligibility requirements. can found on the Blood Portal at: https://www.militaryblood.dod.mil/default.aspx (CAC enabled) >Blood Operations>Blood Program Letters. Download the following documents: AABB Medication List DHQ v.1.3 ASBP Medication List Supplement V.2 Blood Donor Immunizations List						
5.	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 50%; background-color: #cccccc;">If</th> <th style="width: 50%; background-color: #cccccc;">Then</th> </tr> </thead> <tbody> <tr> <td>There are all ‘N’o responses except for question 1.</td> <td>Proceed to Step 6.</td> </tr> <tr> <td>There are any ‘Y’es responses except for question 1.</td> <td>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 all donors that answer yes to questions 2- 6, 10 -20 and 22-35. See notes below for guidance on specific questions. Defer the donor as required, if necessary document “Ineligible” status on DD FORM 572 and in TMDS.</td> </tr> </tbody> </table>	If	Then	There are all ‘N’o responses except for question 1.	Proceed to Step 6.	There are any ‘Y’es responses except for question 1.	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 all donors that answer yes to questions 2- 6, 10 -20 and 22-35. See notes below for guidance on specific questions. Defer the donor as required, if necessary document “Ineligible” status on DD FORM 572 and in TMDS.
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There are any ‘Y’es responses except for question 1.	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 all donors that answer yes to questions 2- 6, 10 -20 and 22-35. See notes below for guidance on specific questions. Defer the donor as required, if necessary document “Ineligible” status on DD FORM 572 and in TMDS.						

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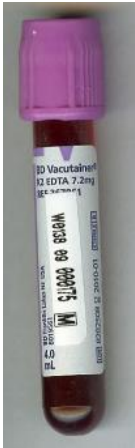
EMERGENCY WHOLE BLOOD COLLECTION SOP

		<p>NOTES: For Q: 4, use AABB Medication List and ASBP Medication List Supplement from ASBPO website (See step 2) to screen for acceptability.</p> <p>For Q: 7, refer to TMDS or Donation Records for last donation date and consult with qualified provider.</p> <p>For Q: 8, refer to Blood Donor Immunization list from ASBPO website (See step 2).</p> <p>For Q: 9, See Donor Acceptability Flowchart to determine donor’s eligibility.</p> <p>For Q: 21, use State Tattoo and Permanent Make-up Reference List. See Tattoo and Make-up Reference List to screen for acceptability.</p> <p>For Q: 36, Refer donor to a qualified provider to determine the donor’s eligibility.</p> <p>For Q: 37: Document the name of the Prophylaxis and accept Donor.</p>						
	6.	<p>Perform and record temperature on Modified DD Form 572. (See DD Form 572–Emergency Whole Blood Donation Record.)</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 50%; text-align: left;">If</th> <th style="width: 50%; text-align: left;">Then</th> </tr> </thead> <tbody> <tr> <td>≤99.5 °F or 37.5 °C</td> <td>Proceed to Step 7.</td> </tr> <tr> <td>>99.5 °F or 37.5 °C</td> <td>Stop the donation process. The donor is “Ineligible” at this time.</td> </tr> </tbody> </table>	If	Then	≤99.5 °F or 37.5 °C	Proceed to Step 7.	>99.5 °F or 37.5 °C	Stop the donation process. The donor is “Ineligible” at this time.
If	Then							
≤99.5 °F or 37.5 °C	Proceed to Step 7.							
>99.5 °F or 37.5 °C	Stop the donation process. The donor is “Ineligible” at this time.							
	7.	<p>Perform and record measurements of donor pulse and blood pressure.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 50%; text-align: left;">If</th> <th style="width: 50%; text-align: left;">Then</th> </tr> </thead> <tbody> <tr> <td>BP ≤ 180/100 and Pulse is ≤ 100 bpm</td> <td>Proceed to Step 8.</td> </tr> <tr> <td>BP >180/100 and Pulse is > 100 bpm</td> <td>Stop the donation process. The donor is “Ineligible” at this time.</td> </tr> </tbody> </table>	If	Then	BP ≤ 180/100 and Pulse is ≤ 100 bpm	Proceed to Step 8.	BP >180/100 and Pulse is > 100 bpm	Stop the donation process. The donor is “Ineligible” at this time.
If	Then							
BP ≤ 180/100 and Pulse is ≤ 100 bpm	Proceed to Step 8.							
BP >180/100 and Pulse is > 100 bpm	Stop the donation process. The donor is “Ineligible” at this time.							
	8.	<p>Perform and record hematocrit/hemoglobin results on Modified DD Form 572, if possible.</p> <p>Male donors do not require hematocrit/hemoglobin testing.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 50%; text-align: left;">If</th> <th style="width: 50%; text-align: left;">Then</th> </tr> </thead> <tbody> <tr> <td>≥38% or 12.5 g/dL</td> <td>Proceed to Step 9.</td> </tr> <tr> <td><38% or 12.5 g/dL</td> <td>Defer donor and stop the donation process. The donor is “Ineligible” at this time.</td> </tr> </tbody> </table>	If	Then	≥38% or 12.5 g/dL	Proceed to Step 9.	<38% or 12.5 g/dL	Defer donor and stop the donation process. The donor is “Ineligible” at this time.
If	Then							
≥38% or 12.5 g/dL	Proceed to Step 9.							
<38% or 12.5 g/dL	Defer donor and stop the donation process. The donor is “Ineligible” at this time.							
	9.	Donor is physiologically acceptable to donate, have the donor sign the Modified DD Form 572 and proceed to Step 10.						
	10.	<p>A competent medical authority should review the Modified DD Form 572 to determine the eligibility of the donor.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 50%; text-align: left;">If</th> <th style="width: 50%; text-align: left;">Then</th> </tr> </thead> <tbody> <tr> <td>Acceptable</td> <td>Donor is “Eligible”. Proceed to Step 11.</td> </tr> <tr> <td>Unacceptable</td> <td>Donor is “Ineligible”. Stop donation process and document deferral as appropriate in TMDS.</td> </tr> </tbody> </table>	If	Then	Acceptable	Donor is “Eligible”. Proceed to Step 11.	Unacceptable	Donor is “Ineligible”. Stop donation process and document deferral as appropriate in TMDS.
If	Then							
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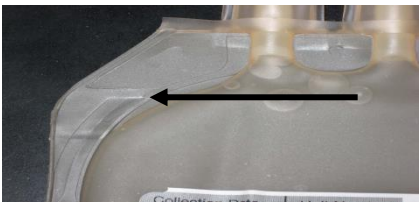
EMERGENCY WHOLE BLOOD COLLECTION SOP

11.	<p>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) and 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.</p>							
Whole Blood Collection								
1.	<p>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.</p> <p>NOTE: If a discrepancy is noted, STOP and correct before proceeding further.</p>							
2.	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; padding: 5px;">If</td> <td style="width: 50%; padding: 5px;">Then</td> </tr> <tr> <td style="padding: 5px;">Yes</td> <td style="padding: 5px;">Skip Step 3 and proceed to Step 4.</td> </tr> <tr> <td style="padding: 5px;">No</td> <td style="padding: 5px;">Proceed to Step 3.</td> </tr> </table>	If	Then	Yes	Skip Step 3 and proceed to Step 4.	No	Proceed to Step 3.	
If	Then							
Yes	Skip Step 3 and proceed to Step 4.							
No	Proceed to Step 3.							
3.	<p>Utilizing Frepp-Sepp, apply Povidone Iodine (Frepp), 2% Aqueous Solution. Scrub vigorously for at least 30 seconds.</p> <p>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</p>							
4.	<p>For donors allergic to iodine, use a chlorohexidene scrub (ChloraPrep). Pinch the wings on the applicator to break the ampule and release the antiseptic. Scrub vigorously for at least 30 seconds.</p> <p>NOTE: If a disinfectant is not available, clean the site with alcohol or other solution, if possible.</p>							
5.	<p>Allow area to dry.</p>							
6.	<p>Set-up trip scale (Manual or Electronic). Perform quality control, if possible, to obtain a counter-weight of 585 grams.</p> <p>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)</p>							

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			<p>The target weight for 450 mL is 585 grams.</p> <p>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.</p>						
	7.	<p>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.</p> <p>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.</p>							
	8.	<p>Apply tourniquet with enough pressure. If using a blood pressure cuff adjust to approximately 40-60 mm Hg.</p>							
	9.	<p>Twist off the needle cover and inspect the needle for barbs or other defects.</p>							
	10.	<p>Pull the skin taut below the venipuncture site.</p>							
	11.	<p>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.</p>							
	12.	<p>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 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.</p>							
	13.	<p>Release the hemostat clamp on the collection bag tubing and observe the blood flow through the tubing and into the collection bag.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 50%; text-align: left;">If blood flow</th> <th style="width: 50%; text-align: left;">Then</th> </tr> </thead> <tbody> <tr> <td>Is impeded</td> <td>Try adjusting the needle with least discomfort without hurting the donor.</td> </tr> <tr> <td>Is still impeded</td> <td>Seek assistance from another phlebotomist before discontinuing the phlebotomy.</td> </tr> </tbody> </table>		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.
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.	<p>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.</p>							
	15.	<p>Instruct donor to relax their grip and to rhythmically squeeze every 5 to 10 seconds, relaxing between squeezes.</p>							
	16.	<p>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.</p>							
	17.	<p>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.</p>							
	18.	<p>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.</p>							

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	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: <ul style="list-style-type: none"> • 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.
	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 tube) 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).

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EMERGENCY WHOLE BLOOD COLLECTION SOP

	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.
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 for 5 minutes at 4000 RPM.
	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.

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	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 <i>with small barcodes</i> . 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. Do not fill over $\frac{3}{4}$ full to allow for expansion from freezing.
	3.	Pour contents of 2 Gold Top tubes into 1 aliquot tube and mark as Serum . Do not fill over $\frac{3}{4}$ 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 transfused.
	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.
	8.	As soon as possible ship samples, Form 145a, Form 148, Form 151 and all DD FORM 572s 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. See USPACOM Key Military Blood Program Directory If shipment is delayed. 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, 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 <i>Technical Manual</i> , current edition AABB <i>Standards for Blood Banks and Transfusion Services</i> JTTS Clinical Practice Guideline: Fresh Whole Blood (FWB) Transfusion Theater Medical Data Store (TMDS) Version 2.7.0.0 System User's Manual	

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EMERGENCY WHOLE BLOOD COLLECTION SOP

Enclosures	DD Form 572–Emergency Whole Blood Donation Record Approved State Tattoo and Permanent Make-up List Donor Acceptability Flow Chart for Question 9 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)
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DD FORM 572-EMERGENCY WHOLE BLOOD DONATION RECORD

Please circle as appropriate:

**WHOLE BLOOD DONATION
PRE-SCREEN**

EMERGENCY WHOLE BLOOD DONATION RECORD (Modified 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: _____ Sex: M/F Weight: _____ ABO/Rh (Blood Type): _____
(DDMMMYYYY) (-110 lbs)
 Deployed Unit/Location: _____ Local DSN Phone: _____ Local Cell/ Evening Phone _____
 Redeployment Date: _____
 Current Residence: Bldg/Tent # _____ RM # _____
 Home Address (Stateside) _____
 Home Phone Number: (____) _____ Email: _____

- | | |
|---|--|
| <p>Y 1. N Are you feeling healthy and well today?
 Y 2. N Are you currently taking an antibiotic?
 Y 3. N Are you currently taking any other medication for an infection?
 Y 4. N Please read the Medication Deferral List. Are you now taking or have you ever taken any medications on the Medication Deferral List?
 Y 5. N In the past 48 hours have you taken aspirin or anything that has aspirin in it?
 Y 6. N In the past 6 weeks, Female donors: have you been pregnant or are you pregnant now?
 Y 7. N In the past 16 weeks have you donated blood, platelets or plasma?
 Y 8. N In the past 8 weeks have you had any vaccinations or other shots?
 Y 9. N In the past 8 weeks have you had contact with someone who had a smallpox vaccination?
 IN THE PAST 12 MONTHS HAVE YOU
 Y 10. N Had a blood transfusion?
 Y 11. N Had a transplant such as organ, tissue, or bone marrow?
 Y 12. N Had a graft such as bone or skin?
 Y 13. N Come into contact with someone else's blood?
 Y 14. N Had an accidental needle-stick exposing you to someone else's blood and/or body fluid?
 Y 15. N Had sexual contact with anyone who has HIV/AIDS or has had a positive test for the HIV/AIDS virus?
 Y 16. N Had sexual contact with a prostitute or anyone else who takes money or drugs or other payment for sex?
 Y 17. N Had sexual contact with anyone who has ever used needles to take drugs or steroids, or anything NOT prescribed by their doctor?
 Y 18. N Had sexual contact with anyone who has hemophilia or has used clotting factor concentrates?
 Y 19. N Female donors: Had sexual contact with a male who has ever had sexual contact with another male?
 Y 20. N Had sexual contact or lived with a person who has Hepatitis
 Y 21. N Had a tattoo or ear/body piercing?
 Y 22. N Had or been treated for syphilis or gonorrhea?
 Y 23. N Been in juvenile detention, lockup, jail, or prison for more than 72 hours?</p> | <p>Y 24. N FROM 1977 TO THE PRESENT, HAVE YOU
 Received money, drugs, or other payment for sex?
 Y 25. N Male donors: had sexual contact with another male, even once?
 HAVE YOU EVER
 Y 26. N Had a positive test for the HIV/AIDS virus?
 Y 27. N Used needles to take drugs, steroids, or anything NOT prescribed by your doctor?
 Y 28. N Used clotting factor concentrates?
 Y 29. N Had Hepatitis after 11th Birthday?
 Y 30. N Had Malaria, Chagas disease, or Babesiosis?
 Y 31. N Received a dura mater (or brain covering) graft?
 Y 32. N Had any type of cancer, including leukemias?
 Y 33. N Had any problems with your heart or lungs?
 Y 34. N Had a bleeding condition or a blood disease?
 Y 35. N Have any of your relatives had Creutzfeldt-Jakob disease?
 Y 36. N In the past 12 months, have you been under a doctor's care for an illness or surgery?
 Y 37. N Are you currently taking malaria prophylaxis if required?</p> |
|---|--|

(Use this section and reverse side of form to explain "Yes" answers above. With the exception of question 1.)

Medications: _____ Donor: Temp: _____ °F/°C BP: _____ / _____ Pulse: _____ HCT/Hgb: _____
(= 99.6°F/37.5°C) (= 180/100) (= 100 bpm) (= 38% or 12.5 g/dL)

Your blood **will NOT be tested** for viral diseases prior to transfusion due to the emergency. If for any reason you feel your blood may not be safe, please do not donate today.

I 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: _____

Reviewer: _____ Date: _____ TMDS/TBLD entered by: _____ (initials)/ _____ (Date)

This Modified DD Form 572 is to be used only in a deployed/contingency environment for collection of emergency whole blood.

DD 572 (WB)
Version: 28 August 2014

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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) applied by a state-regulated entity, (b) with sterile needles, (c) and ink that has not been reused. 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 ink that has not been reused. 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	YES	

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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	YES	
Mississippi	YES	
Missouri	YES	
Montana	YES	
Nebraska	YES	
Nevada	NO	
New Hampshire	NO	
New Jersey	YES	

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BPL 13-08

BPL Date 30-Oct-13

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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	

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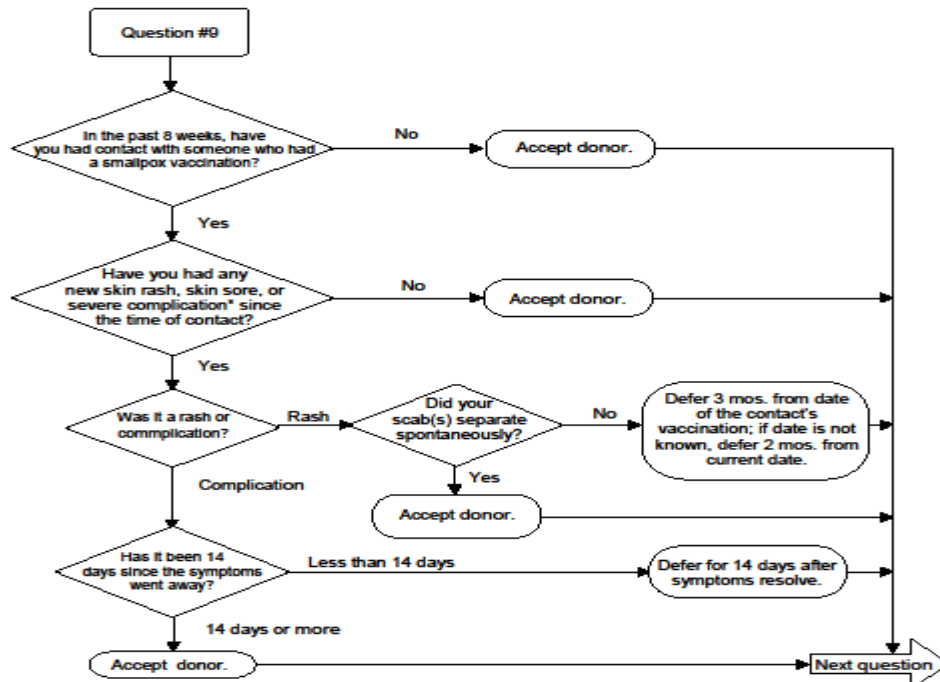
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Donor Acceptability Flow Chart for Question 9

Question: 9. In the past 8 weeks, have you had contact with someone who had a smallpox vaccination?

Donor Eligibility: Certain vaccinations may contain live infectious agents. A donor who has had close contact with the vaccination site, bandages covering the vaccination site or materials that might have come into contact with an unbandaged vaccination site, including clothing, may be exposed to the live infectious agents and should not be a donor for a specified period of time.



*Severe complications include the following: rash (resembling blisters) covering a small or large area of the body; necrosis (tissue death) in the area of exposure; encephalitis (inflammation of the brain); infection of the cornea (eye); and localized or systemic skin reaction in someone with eczema or other chronic skin condition.

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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	<p>Do not collect from donors currently on antibiotics, to exclude anti-malarial prophylaxis.</p> <p>Donors taking medications that the competent medical authority deems may cause harm to the recipient must be deferred from donating.</p> <p>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.</p>
Medical Conditions	<p>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.</p>

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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

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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) <input type="checkbox"/> RED BLOOD CELLS <input type="checkbox"/> FRESH FROZEN PLASMA <input type="checkbox"/> PLATELETS (Pool of _____ units) <input type="checkbox"/> CRYOPRECIPITATE (Pool of _____ units) <input type="checkbox"/> Rh IMMUNE GLOBULIN <input type="checkbox"/> OTHER (Specify) _____		TYPE OF REQUEST (Check ONLY if Red Blood Cell Products are requested.) <input type="checkbox"/> TYPE AND SCREEN <input type="checkbox"/> CROSSMATCH DATE REQUESTED _____ DATE AND HOUR REQUIRED _____	
VOLUME REQUESTED (If applicable) _____ ML		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.	
REMARKS: _____ _____		KNOWN ANTIBODY FORMATION/TRANSFUSION REACTION (Specify) _____ SIGNATURE OF VERIFIER _____ 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. _____ DONOR _____ ABO _____ Rh _____	TRANSFUSION NO. _____ PATIENT NO. _____ RECIPIENT _____ ABO _____ Rh _____	TEST INTERPRETATION ANTIBODY SCREEN _____ CROSSMATCH _____ <input type="checkbox"/> CROSSMATCH NOT REQUIRED FOR THE COMPONENT REQUESTED REMARKS: _____	PREVIOUS RECORD CHECK: <input type="checkbox"/> RECORD <input type="checkbox"/> NO RECORD SIGNATURE OF PERSON PERFORMING TEST _____ DATE _____
SECTION III – RECORD OF TRANSFUSION			
PRE-TRANSFUSION DATA INSPECTED AND ISSUED BY (Signature) _____ AT (Hour) _____ ON (Date) _____		POST-TRANSFUSION DATA AMOUNT GIVEN _____ ML TIME/DATE COMPLETED/INTERRUPTED _____ REACTION: <input type="checkbox"/> NONE <input type="checkbox"/> SUSPECTED TEMPERATURE _____ PULSE _____ BLOOD PRESSURE _____	
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) _____		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 <input type="checkbox"/> URTICARIA <input type="checkbox"/> CHILL <input type="checkbox"/> FEVER <input type="checkbox"/> PAIN <input type="checkbox"/> OTHER (Specify) _____ OTHER DIFFICULTIES (Equipment, clots, etc.) <input type="checkbox"/> NO <input type="checkbox"/> YES (Specify) _____	
PRE-TRANSFUSION TEMP. _____ PULSE _____ BP _____ DATE OF TRANSFUSION _____ TIME STARTED _____		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, FIRM (41 CFR) 201-9.202-1			

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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

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WBB SUPPLY LIST (WITH NSNs)

Item Description	Stock# / NSN #
SHARPS Container	6515014922824
Biohazard Bags	6530013806463
Leak Resistant Chucks	6530011190015
Gloves-SM	6515014618939
-MED	6515014618933
-LRG	6515014618933
Surgical Tape	6510009268882
Sphygmomanometer	6515015104342
Stethoscope	6515013146694
Tempa Dots	6515015230998
Lancet	6515004312890
Alcohol Pads	6510007863736
2x2 Gauze	6510007822700
STAT SiteM	6640015089027
STAT SiteM Test Cards	6550015096101
STAT SiteM HGB Control	6550015110388
Blood Bag Scales-Hemo Flow	6515015137010
Blood Bag Stand	6515004114375
Terumo Single Blood Bags	6515014802307
Frepp/Sepp Kit	6510011139208
4x4 Gauze	6510007822698
Hand Stripper/Sealer/Cutter	6515011405267
Hand Sealer Clips	6515010701532
Scissors	6515003650640
Hemostats	6515003346800
Adapter MS DIR 100S Luer 100S	6515014328272
Purple Top (EDTA Plasma)	6640013780086
Pearl Top (PPT)	6640015735282
Gold Top (SST)	6640013678991
Coban 5x1	6510001055807
Eldon Card (Rapid ABO/Rh)	6515015396531
HIV 1/2 RA OraQuick	6550015267424
ORAQUIK HCV	6550015899845
ONSITE (CTK) HBSAG (Hep B)	6550015266009
Malarial Rapid Test	6550015548731
RPR Test Kit	6550015110291

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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.