FRESH WHOLE BLOOD (FWB) TRANSFUSION

Original Release/Approval		Oct 2006	Note: This CPG requires an annual review.
Reviewed:	Feb 2011	Approved:	18 Mar 2011
Supersedes:	Fresh Whole Blood (FWB) Transfusion, updated 19 Nov 08		
☐ Minor Changes (***or)***		X ***Changes are substantial and require a thorough reading of this CPG***	***(or)***
☐ Significant Changes:			

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

2. Background. Whole blood has been used extensively to resuscitate casualties in military conflicts since World War I. Its use in civilian settings is limited due to the wide availability of fractionated components derived from whole blood and provided for specific deficits (e.g., pRBCs for anemia, fresh frozen plasma (FFP) to replace lost/consumed clotting factors, platelets (PLTS) for thrombocytopenia, cryoprecipitate (Cryo) for hypofibrinoginemia.) However, in austere conditions, fractionated blood products are often 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*).

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:PLTSs 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 readily 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 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 frequently 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 during OIF/OEF have resulted in one 1 Hepatitis C seroconversion. Fresh whole blood 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 (e.g. Level III facilities):* 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 (i.e., Level I and II facilities):* FWB should only be used when there is a threat to loss of life, limb or eye-sight. A walking blood bank program will be established based on a risk assessment and the potential for casualties. Coordination with the Area Joint Blood Program Officer is required to establish a walking blood bank.

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. 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. 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.**

d. 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.

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 transfusion equipment may lead to coagulation during the transfusion process; therefore only authorized equipment will be utilized (Appendix B enclosure 6).

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.

a. Establish a pre-screened donor pool using the Blood Donation Questionnaire (DD Form 572 or MS Word version), preferably composed of active duty, active reserve, active National Guard, and other DoD beneficiaries. Testing of the potential donor pool for transfusion-transmitted diseases should be also be performed. Coalition and Foreign Nationals will not be routinely utilized as donors, only by exception. Recent laboratory confirmation of blood group/type and non-reactive status for transfusion-transmissible disease tests is ideal, but does not obviate the need for confirmatory testing. The donor file must be maintained and updated frequently.

b. In an emergency, rapidly establish ABO/Rh status of donors and casualties on-site using appropriate reagents/tests in conjunction with previous blood donor history records, if available.

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

d. 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.

e. It is highly recommended, to perform on-site testing of potential blood donors using rapid screening immunoassays for infectious diseases (i.e., HIV, HBV, HCV) before FWB is transfused. Regardless whether the local testing is performed pre- or post-transfusion, these tests are not licensed for donor testing and samples must be sent to a reference lab for FDA-approved testing. A mechanism must be in place to ensure that both the recipient and donor can be notified should the results be positive for infectious disease.

f. 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).

g. **Procedure**. See Appendix B for Emergency Fresh Whole Blood Donation.

7. References:

1. 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. CENTCOM FRAGO 09-1222: *Joint Theater Blood Program Update*: 4 May 2007
3. *Emergency War Surgery*, 2004, Third US Revision, Chap 7: Shock and Resuscitation
4. Theater MTF-specific Standard Operating Procedures (SOPs)
5. Technical Manual, AABB, Bethesda Maryland, 16th Edition, 2008
6. Standards for Blood Banks & Transfusion Services, AABB, 25th Ed, February 2008

Approved by CENTCOM JTTS Director, JTS Director and Deputy Director and CENTCOM SG

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

APPENDIX A

1. Background: In every conflict since World War I, the military has used whole blood in the resuscitation of combat casualties. In fact, LTG Leonard Heaton once stated that, *"If any single medical program can be credited with the saving of countless lives in World War II and the Korean War, it was the prompt and liberal use of whole blood."* However, following the development of fractionation techniques in the 1950s, the use of whole blood was largely abandoned in civilian trauma centers in favor of blood component therapy. Because the military often practices in austere and remote environments where platelets and FFP are unavailable and even red blood cell supplies are limited, fresh whole blood (FWB) is frequently the only option for transfusion.

As more sophisticated medical assets are pushed closer to the front, military physicians find they have more choices. While FWB is clearly effective, **prospective randomized trials have not been performed comparing its use to component therapy**, which is now more widely available. Similarly, while the risks of banked blood are well known, the risks of untested FWB collected from deployed donors in a field environment are, as yet, uncharacterized. To make an informed decision regarding the use of FWB, physicians must understand the risks and benefits of FWB compared to those of available component therapy.

2. Evidenced-based Review: Prospective FWB donors in-theater are generally young, healthy active duty service members who receive comprehensive preventive health care including vaccination for hepatitis B and regular screening for HIV. Despite these precautions, some transfusion-transmitted infections do not have effective vaccines and are not screened prior to deployment (i.e., HCV, HTLV, syphilis). Furthermore, other transfusion-transmitted infections such as malaria and Leishmaniasis are endemic in many areas where military personnel are deployed. Although presumably low, the prevalence of these infections among prospective donors in theater is unknown.

The FDA has rigorous standards for testing of blood products for transfusion-transmitted infections. CENTCOM guidance on whole blood transfusion highly recommends that both pre-transfusion and post-transfusion testing be performed. These tests include rapid viral tests for HIV-1/2, HBV, and HBC. At the present time, these testing kits are available to all facilities where FWB may be collected and transfused.

In approximately 5,300 emergency FWB transfusions in OIF and OEF there has been one identified seroconversion to Hepatitis C. In a retrospective analysis of over 2800 units transfused 3 of these units were positive for hepatitis C, a rate of .11% (Spinella, et al Crit Care Med 2007;35:2576). Whatever the risk of transmitting an infectious disease by transfusing FWB collected in-theater (even if untested), it is clearly much smaller than the risk of death from hemorrhagic shock (<1% compared to 30-50%). However, with increased availability of a variety of banked blood components, military physicians now may have other options besides FWB and pRBCs. While FWB may be the only choice at a Level II facility when platelets are needed, the blood bank capabilities at Level III facilities approach those of a civilian trauma center. In that setting, the beneficial effects of fresh whole blood compared to component therapy remain controversial.

The actual process of collecting and transfusing FWB in the combat environment presents several logistical problems. While blood donor centers in the US are highly regulated with

respect to donor screening procedures, quality control and testing protocols, staff training requirements, and even the physical facility requirements, the collection of whole blood in the field is often performed under less than optimal conditions. Because they are generally not staffed for emergency blood collection, the laboratory often must suspend other activities (e.g., routine labs and blood testing) in order to collect and process the FWB. Finally, because FWB is generally required emergently, the donor site staff may be more prone to technical and clerical errors, particularly when more than one blood type is being collected; as in a MASCAL situation.

On the other hand, several authors have shown that by reducing the total number of blood products transfused, the use of whole blood actually reduces the chance of clerical errors in the operating room. Importantly, in cases requiring rapid and massive transfusion where ease of administration is important, FWB clearly has an advantage over component therapy.[1] Repine, et al., cite numerous examples of emergency whole blood drives, pointing out that *"once donor populations are defined and characterized in a massive transfusion or mass-casualty situation, the logistical balance tilts toward the utilization of whole blood."* [2] The use of FWB clearly reduces the logistical burden at the bedside, providing for simpler and more rapid transfusion of blood.

It has been suggested that because FWB contains fresher, more functional components which are present in more physiologic concentrations, it should be more effective than banked blood. It is well known that banked red blood cells develop a so-called "storage lesion" (i.e., decreased nitric oxide, decreased pH, decreased 2,3-DPG, decreased ATP) which reduces oxygen-carrying capacity. Other drawbacks of banked blood include hyperkalemia from increases in extracellular potassium during storage, and hypothermia. Some researchers have linked such changes to adverse clinical outcomes.[3] This must be kept in mind while dealing with military trauma casualties with multiple massive injuries and severely compromised physiology. Use of fresher blood (<14 days of storage) and blood warmers should mitigate some of these problems. Currently, USCENTCOM is moving pRBCs into Balad, Baghdad, and Bagram that are <14 days of age for use in the massive transfusion patients.

It has also been suggested there are increased levels of inflammatory mediators in banked blood, which may lead to adverse outcomes.[4] These findings were not confirmed in a 2004 article,[5] but this may be secondary to the use of leukocyte-reduced products. Many of the drawbacks of banked blood cited in older literature have been addressed by measures such as the development of improved additive solutions, the routine use of leukocyte-reduction (particularly at donation), and the advent of apheresis platelets. Despite these improvements recent reports still indicate that leukoreduced RBCs are independently associated with increased mortality in trauma patients and the storage age of RBCs is directly related to this relationship.[7]

To date, there have been no prospective randomized clinical trials comparing FWB to component therapy in the trauma setting. One large retrospective analysis of over 350 patients transfused blood during OIF showed a significant survival benefit to patients receiving at least one unit of fresh whole blood as a component of their resuscitation. [8]

3. Conclusion. Despite the fact that fresh whole blood is unlikely to become an FDA-approved therapy, given the exigencies of the circumstances within which the military medicine community must operate, this therapy will continue to be a lifesaving addition to the

armamentarium of those caring for seriously injured warfighters. It is important for the health care provider to understand the risks associated with this therapy, and to balance these risks with the potential benefit to the patient when choosing this therapy.

4. References

[1] Laine, et al., *Transfusion*, 2003, 43:322-327.

[2] Repine, et al., *J Trauma*, 2006, 60(6S):S59-69

[3] Ho, et al., *Crit Care Med*, 2003, 31(12S):S687-697

[4] Silliman, et al., *J Lab Clin Med*, 1994, 124(5):684-94

[5] Mou SS, et al, *N Engl J Med* 2004, 351(16):1635-1644

[6] Lavee, et al., *J Thorac Cardiovasc Surg*, 1989, 97:204-212

[7] Weinberg, J Trauma 2008, Spinella PC Crit Care Med 2008

[8] Spinella, et al, ATACCC, 2008

APPENDIX B

EMERGENCY FRESH WHOLE BLOOD DONATION

Overview

Introduction

This standard operating procedure describes how to pre-screen prospective donors, and collect and process whole blood for transfusion and blood samples for infectious disease testing (rapid and transfusion transmitted diseases (TTD)). **FWB collected must be the same blood type as the patient.** A minimum of 30-50 donors (e.g., 20 "O", 20 "A", and 10 "B").

Identification tags for ABO/Rh verification will be utilized only as a last resort.

Documentation

Attached are standardized forms to be used to document donor screening, and rapid testing results. Additionally, the Blood Inventory Management (eMOAS) System using Theater Management Data System (TMDS) should be used to record donor demographic and test result information (see eMOAS SOP#4). A list of material/equipment with NSNs is enclosed.

Summary of Changes

Apr 2010, Original Issue

References

The following references were used in the preparation of this procedure:

1. FM 4-02.70; NAVMED P-5120; AFMAN (I) 41-111, Standards for Blood Banks and Transfusion Services, Current Edition, American Association of Blood Banks.
2. Code of Federal Regulations, Title 21, Parts 600-799, Washington, DC, U.S. Government Printing Office, Current Edition.
3. OASD(HA) dated XX MMM YY, Policy on the Use of Non-US Food and Drug Administration Compliant Blood Products.
4. Armed Services Blood Program Blood Policy Letter for Tattoos.
5. Lackland AFB Blood Donor Center, Donor Sample Submission Requirements
6. Blood Inventory Management (eMOAS) System Standard Operating Procedure #4, Manage Donation, Version 1.0, 18 Mar 2010.

Approval Signature

_____ _____

Joint Theater Blood Program Officer Date

For questions, contact the Area JBPO or COCOM Joint Blood Program Officer at:

MacDill AFB - DSN: 312-651-6397

Al Udeid AB - DSN: 318-436-4116

Purpose

This instruction provides guidance on pre-screening prospective donors and collecting fresh whole blood (FWB) from qualified donors. Prospective donors will complete a modified donor questionnaire (DD Form 572-Modified) and have blood samples collected for infectious disease testing using rapid test kits and FDA licensed testing to qualify a donor for the Walking Blood Bank (WBB) Program.

- If acceptable, the donor should be recorded on a WBB Program roster.
- If unacceptable, the donor should be referred to a medical or public health provider, as necessary, for further evaluation, and notified of the time frame for deferral from donation.

Upon the activation of the WBB Program, qualified personnel will perform the steps outlined to collect a unit of FWB, and ensure the proper labeling of the unit and samples for infectious disease testing (rapid and TTD).

eMOAS will be used to record the following information for pre-screening and whole blood donations (see eMOAS SOP #4).

- Donor demographic information
- Rapid testing results
- Transfusion transmitted disease results
- Donor alerts

The following list of materials and equipment is recommended; however, at lower echelons of care modified steps without equipment may be performed.

See *Enclosure 6* for a list of material/equipment with NSNs.

Note: Units/commands should use manufacturer inserts and/or standard operating procedures for the performance of rapid testing and equipment maintenance.

<u>Blood Collection</u>

- WBB Program Roster (Database or eMOAS Ad Hoc Report)
- Emergency Donation Record (DD Form 572 – Modified)
- Donation Identification Numbers (Use donor SSN if not available)
- Direct Oral Questions
- State Tattoo and Permanent Mark-Up Reference List
- Blood Collection Table or Reclining Chair
- Blood Collection Bags (Terumo – Single Blood Bag (SCD 4564A))
- Adapter MS DIR Luer (100s)
- Blood Trip Scale (Manual or Electronic)

Blood Collection (Continued)

- Skin Disinfectant Solution (Frepp-Sepp, Alcohol, or other)
- Gloves
- Tourniquet
- Hemostats
- Scissors
- Blood Tube Strippers
- Metal Clips
- Gauze
- Adhesive Tape
- Biohazard Container/Sharps Container

Donor Health Screening

- Thermometer (Digital, Temp-a-Dot, or other device)
- Hemoglobin Testing Equipment (If possible)

Donor Blood Sample Containers

- Golden Top Tube (SST) – 2
- Pearl Top Tube (PPT) – 2
- Purple Top Tube (EDTA) – 1
- Aliquot Tubes – 2
- Centrifuge

Donor Blood Testing

- Eldon ABO/Rh Testing Card
- Rapid HIV
- Rapid HCV
- Rapid HBsAg
- Syphilis Test, Serological (RPR)
- Malaria
- Clinical Rotator (Required for Syphilis Test)
- Disposable Pipettes
- Lancet

Procedural Note/Warning

To the maximum extent possible, Medical Treatment Facilities (MTFs) and U.S. Navy vessels will establish and maintain rosters of pre-screened donors, and repeat the screening at regular intervals (not to exceed 90 days). Retrospective testing following an emergency blood donation may serve as a pre-screen for a subsequent donation.

FWB will have a shelf-life of 24-hours and should be stored at 1-6° within 8-hours after collection, unless otherwise directed by medical staff due to insufficient or no red blood cell (RBC) or plasma product inventory.

Identify a blood donor who is ABO-identical with the intended recipient. (ABO and Rh idenctical for women of child bearing age)>

Screening Donor

Perform the following steps when screening donors for the WBB Program and before the collection of FWB.

Note: Personnel who are actively donating blood in the military or a civilian blood program should be sought after for enrollment in the WBB Program.

<table>
<tr><th>ID</th><th>Description</th></tr>
<tr><td>1.</td><td>Identify personnel for each donor screening and blood collection stations: Registration; Interview; Mini-Physical Exam; and Phlebotomy. Ensure space is as clean as possible and will allow for conducting a safe process.</td></tr>
<tr><td>2.</td><td>Give donor Emergency Donation Record (Modified DD Form 572 (Enclosure 1)) and instruct donor to complete demographic information and to answer questionnaire by circling ‘Y’es or ‘N’o.</td></tr>
<tr><td>3.</td><td>A qualified interviewer will review the completed Modified DD Form 572.
<table>
<tr><th>If…</th><th>Then…</th></tr>
<tr><td>There are all ‘N’o responses except for questions 22-24</td><td>Proceed to Step 4.</td></tr>
<tr><td>There are any ‘Y’es responses except for questions 22-24</td><td>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 circle “Ineligible” and sign.</td></tr>
</table>
Note: For Q: 39, use State Tattoo and Permanent Make-up Reference List (Enclosure 2) to screen for acceptability.</td></tr>
</table>

<table>
<tr><th>ID</th><th>Description</th></tr>
<tr><td>4.</td><td>Using the Direct Oral Questions (Enclosure 3), ask the donor Group A, B, and C questions. Record name of interviewer on Modified DD Form 572.
<table>
<tr><th>If…</th><th>Then…</th></tr>
<tr><td>The donor answers ‘N’o to each group</td><td>Proceed to Step 5.</td></tr>
<tr><td>The donor answers ‘Y’es to any group</td><td>Defer donor for designated period of time and stop the donation process. Circle “Ineligible” and sign.</td></tr>
</table></td></tr>
<tr><td>5.</td><td>Perform and record temperature on Modified DD Form 572.
<table>
<tr><th>If…</th><th>Then…</th></tr>
<tr><td><99.6 ºF or 37.5 ºC</td><td>Proceed to Step 6.</td></tr>
<tr><td>>99.6 ºF or 37.5 ºC</td><td>Defer donor and stop the donation process. Circle “Ineligible” and sign.</td></tr>
</table></td></tr>
<tr><td>6.</td><td>For female donors, perform and record hematocrit/hemoglobin results on Modified DD Form 572, if possible.

Male donors do not require hematocrit/hemoglobin testing.
<table>
<tr><th>If…</th><th>Then…</th></tr>
<tr><td>>38% or 12.5 g/dL</td><td>Proceed to Step 7.</td></tr>
<tr><td><38% or 12.5 g/dL</td><td>Defer donor and stop the donation process. Circle “Ineligible” and sign.</td></tr>
</table></td></tr>
<tr><td>7.</td><td>If donor is accepted to donate, have the donor sign the Modified DD Form 572.</td></tr>
<tr><td>8.</td><td>A competent medical authority should review the Modified DD Form 572 to determine the eligibility of the donor.
<table>
<tr><th>If…</th><th>Then…</th></tr>
<tr><td>Acceptable</td><td>Circle “Eligible” and sign. Go to next Section for the collection of blood samples for infectious disease testing.</td></tr>
<tr><td>Unacceptable</td><td>Circle “Ineligible,” record reason for unacceptability and sign. Defer donor and stop the donation process.</td></tr>
</table></td></tr>
<tr><td>9.</td><td>Maintain Modified DD Form 572 in a central file in preparation for activating the WBB.</td></tr>
</table>

Donor Samples for Testing

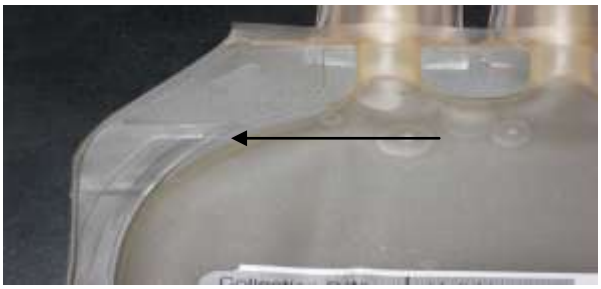
Perform the following steps on acceptable donors for the performance of rapid and TTD testing.

ID	Description
1.	Collect by venipuncture or during FWB collection: 1 Purple Top (EDTA), 2 Pearl Tops (PPT), and 2 Gold Tops (SST).
2.	Label sample tubes with the donor's Donation Identification Number (DIN) labels without barcodes, or the donor's SSN and Full Name if labels are not available. 
3.	Record the DIN on the Modified DD Form 572 located in the top right-hand corner. If no DIN labels are available, use the donor's SSN.
4.	Centrifuge Pearl and Gold Top Tubes for adequate plasma and serum separation.
5.	Perform HIV, HCV, HBsAg, RPR, and as required, Malaria test, in accordance with the manufacturer's insert or standard operating procedure. Record results on Rapid Testing Worksheet (*Enclosure 4*); transcribe results into eMOAS IAW SOP #4.
6.	Perform Eldon (ABO/Rh) using Purple Top (EDTA) or by finger-stick with Whole Blood.
7.	Label four (4) aliquot (pour off) tubes with corresponding DIN labels with barcodes, or donor's SSN if labels are not available. 
8.	Pour each Pearl (2) and Gold Top (2) Tube into its own aliquot tube. **Note:** A minimum of 3 mL is required in each aliquot tube.
9.	As soon as possible, ship samples to nearest medical facility or blood support unit with a copy of the Modified DD Form 572. The medical facility or blood support unit will be responsible for shipping samples to testing center (e.g., Wilford Hall RMC). **Note:** Freeze samples if testing will not be performed within 7 days.
10.	Notify receiving facility that the specimens are en route by e-mail or with a phone call.

Note: See *Enclosure 5* for additional details for submitting samples to Lackland AFB Blood Donor Center.

Fresh Whole Blood Collection

Perform the following steps to collect FWB as directed in accordance with the Joint Theater Trauma System Clinical Practice Guidelines for the transfusion of FWB or medical staff.

ID	Description
1.	Utilize unit/command process to activate the WBB Program and to notify donors who have been previously screened and tested with negative results.
2.	Set-up blood donor bed or reclining chair.
3.	Set-up trip scale (Manual or Electronic). Perform quality control, if possible, to obtain a counter-weight of 585 grams. **Note:** If no trip scale is available, and if using the Terumo Single Blood Bag, fill bag with whole blood to the mark as indicate by the arrow below.  The target weight for 450 mL is 585 grams (bag w/ anti-coagulant). Do not use if: Overfilled - > 650 grams
4.	Follow procedure above for **Screening Donor**. **Note:** Based on emergent need for FWB, at a minimum the donor will review the most recently complete Modified DD Form 572 to ensure no information has changed. Document on the Modified DD Form 572 that the donor has reviewed the form and states that no information has changed.
5.	Label Modified DD Form 572, the blood bag, and samples tubes (2 – Pearl Tops, 2 – Gold Tops, and 1 Purple Top) with the Donor Identification Number (DIN). If no DIN labels are available, use the donor's SSN (See labeling instruction above).
6.	Issue DIN labeled blood bag and sample tubes with the Modified DD Form 572 to the donor (or phlebotomist).
7.	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, and that the DIN are the same on the blood bag, sample tubes, and Modified DD Form 572. **Note:** If a discrepancy is noted, STOP and correct before proceeding further.
8.	Clean donor arm with Skin Disinfectant Solution (Frepp-Sepp, Alcohol, or other) at least 3 inches in diameter from the anticipated site of the venipuncture and allow to dry. **Note:** Follow manufacturer's instructions on the box or packaging.

<table>
<tr><th>ID</th><th>Description</th></tr>
<tr><td>9.</td><td>Place a knot in the tubing approximately 6 inches from the needle if metal seal clips with hand crimpers are not available.</td></tr>
<tr><td>10.</td><td>Using hemostats, 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.</td></tr>
<tr><td>11.</td><td>Apply tourniquet with enough pressure. If using a blood pressure cuff adjust to approximately 40-60 mm Hg.</td></tr>
<tr><td>12.</td><td>Twist off the needle cover and inspect the needle for barbs or other defects.</td></tr>
<tr><td>13.</td><td>Pull the skin taut below the venipuncture site.</td></tr>
<tr><td>14.</td><td>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.</td></tr>
<tr><td>15.</td><td>When the bevel is completely under the skin, lower the angle of the needle to approximately 10º or less and, with a steady push, advance needle to penetrate the vein wall. Thread needle approximately ½ inch inside the vein to maintain a secure position and to lessen the chance of a clot forming.</td></tr>
<tr><td>16.</td><td>Fill sample tubes using the tube adaptor. After filing pilot tubes, verify once again that donation identification number on tubes corresponds to donation identification number on the collection bag.</td></tr>
<tr><td>17.</td><td>Release the hemostat clamp on the collection bag tubing and observe the blood flow through the tubing and into the collection bag.
<table>
<tr><th>If blood flow…</th><th>Then…</th></tr>
<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>
</table></td></tr>
<tr><td>18.</td><td>Instruct donor to relax their grip and to rhythmically squeeze every 5 to 10 seconds, relaxing between squeezes.</td></tr>
<tr><td>19.</td><td>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.</td></tr>
<tr><td>20.</td><td>Partially reduce the pressure by loosening the tourniquet or blood pressure cuff to approximately 20-40 mm Hg.</td></tr>
<tr><td>21.</td><td>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 Hematoma.</td></tr>
</table>

ID	Description
22.	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.
23.	Record the following in the appropriate blocks on the DD Form 572: Time phlebotomy was started. Initials of the phlebotomist.
24.	Watch for the signal of a filled unit by monitoring for the completion indicator of a weighing device or mark on the bag. Mentally note the time this happens, as this is the time the phlebotomy is completed.
25.	Place hemostats 3-4 inches from the needle.
26.	Seal the tubing 1 to 2 inches below the "Y" segment of the tubing by pulling on tubing to create a tight knot, or using the metal seal slips with hand crimpers.
27.	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.
28.	Remove tourniquet or blood pressure cuff and tape strips from donor's arm.
29.	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.
30.	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.
31.	Discard the needle assembly into a sharps container.
32.	Using a hand stripper/crimper, strip all blood from the tubing into the primary collection bag. This should be done ASAP after collection.
33.	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.
34.	Take donor unit and donor sample tubes (2 gold tops (SST), 2 pearl tops (PPT), and 1 purple top tubes) to processing area.
35.	Strip donor unit tubing three times and mix blood by rocking back and forward to prevent clot formation.
36.	Write the expiration of the unit, which is 24 hours from collection
37.	Perform ABO/Rh typing utilizing Eldon Card Kit and purple top tube.
38.	Write the donor blood type **on the bag** (Eldon Card results) along with date, time and phlebotomist initials of collection.

ID	Description
39.	Follow procedure above for **Donor Samples for Testing**.
40.	Record FWB collection in eMOAS with rapid testing results. TTD results will be entered into eMOAS by the blood support unit or as otherwise directed.

Enclosures	
1.	Emergency Whole Blood Donation (Modified DD Form 572)
2.	State Tattoo and Permanent Make-Up Reference List
3.	Direct Oral Questions
4.	Rapid Testing Worksheet
5.	Donor Sample Submission Requirements (dtd 15 Mar 2010)
6.	Equipment and Materials List with NSNs

Coordination and Implementation

Facility	

Procedure Information	**Procedure No**:	**Revision Date**: Apr 2010
	Title: Emergency Fresh Whole Blood Donation	
	Total Pages: 10	**Date Implemented**:

Coordination Signatures

This procedure has been reviewed by the following individuals at the local facility:

Coordinated with...	Signature	Date
Medical Director		
Quality Assurance Coordinator		
OIC, Blood Bank		
Technical Supervisor, Blood Bank		
NCOIC, Blood Bank		

Document Control

The total number of copies made for local use is ____ and their locations are:

Copy #	Location	Copy #	Location
Master		5	
1		6	
2		7	
3		8	
4		9	

Annual Review

Facility

Procedure Information

Procedure No: eMOAS SOP #4	**Revision Date**:
Title: Emergency Fresh Whole Blood Donation	
Total Pages: 11	**Date Implemented**:

Review Signatures

This procedure has been reviewed by the following individuals at the local facility:

Reviewed by:	Signature	Date

Enclosure 1, Emergency Whole Blood Donation (Modified DD Form 572)

EMERGENCY WHOLE BLOOD DONATION RECORD

(Modified Version of the DD Form 572)

Blood Unit Number

Use Donor SSN if ISBT # Not Available

MTF/Location: _____ Donation Date: _____

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

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

Deployed Unit/Location: _____ Local DSN Phone: _____ Redeployment Date: _____

Current Residence: Bldg/Tent # _____ RM # _____

Home Address (Stateside) _____

Home Phone Number: (____) _____ Email: _____

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

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

High Risk Oral Questions (30May2003) Asked By: _____ Donor: Temp: ____°F/°C (< 99.6°F/37.5°C) BP: ____/____ (≤ 180/100) Pulse: _____ (< 100 bpm) HCT/Hgb: _____ (> 38% or 12.5 g/dL)

31. Medications: _____

Malaria Prophylaxis: Daily____(Doxycycline) Weekly____(Mefloquin) N/A _____

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

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

Donor's Signature

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

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

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

DD 572 (WB)
Version: 13 August 2009

Enclosure 2, State Tattoo and Permanent 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. Changes from the 21 March 2008 publication are highlighted in yellow.

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

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

STATE	ACCEPTABILITY	NOTE
Alabama	Yes	n/a
Alaska	Yes	n/a
Arizona	Yes	n/a
Arkansas	Yes	n/a
California	No	n/a
Colorado	Yes	n/a
Connecticut	No	n/a
Delaware	Yes	n/a
District of Columbia	No	n/a
Florida	No	n/a
Georgia	No	n/a
Hawaii	Yes	n/a
Idaho	No	n/a
Illinois	No	n/a
Indiana	Yes	n/a
Iowa	Yes	n/a
Kansas	Yes	n/a
Kentucky	Yes	n/a
Louisiana	Yes	n/a
Maine	Yes	n/a
Maryland	No	n/a
Massachusetts	No	n/a
Michigan	No	n/a
Minnesota	No	n/a
Mississippi	Yes	n/a
Missouri	Yes	n/a
Montana	Yes	n/a
Nebraska	Yes	n/a
Nevada	No	n/a

10 August 2010 Page 1 of 2 Attachment 2

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

STATE	ACCEPTABILITY	NOTE
New Hampshire	No	n/a
New Jersey	Yes	n/a
New Mexico	No	n/a
New York	No	n/a
North Carolina	Yes	n/a
North Dakota	No	n/a
Ohio	Yes	n/a
Oklahoma	No	n/a
Oregon	Yes	n/a
Pennsylvania	No	n/a
Rhode Island	Yes	n/a
South Carolina	Yes	n/a
South Dakota	Yes	n/a
Tennessee	Yes	n/a
Texas	Yes	n/a
Utah	No	n/a
Vermont	Yes	n/a
Virginia	Yes	n/a
Washington	Yes	If prior to 1 July 2010, defer 12 months.
West Virginia	Yes	n/a
Wisconsin	Yes	n/a
Wyoming	No	n/a

10 August 2010 Page 2 of 2 Attachment 2

Enclosure 3, Direct Oral Questions

DIRECT ORAL QUESTIONS

PREAMABLE

I am required to ask you some questions. If you do not understand a question, please ask me to explain it before answering. The reason for asking these questions is to determine your suitability as a volunteer blood donor. Your answers to these questions will be kept strictly confidential, but may result in you being asked not to donate blood, either temporarily or permanently. Do not respond until I have asked you the entire group of questions, which at that time only give me one answer – Yes or No.

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?

IF Response is	THEN
No	Proceed to Group C
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 to listed Countries	Proceed to Group C
YES to listed Countries	**Document when, DEFER INDEFINITELY**

(A "Yes" answer to Group B may be an Indefinite Deferral)

GROUP C:

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

(A "Yes" answer to Group C is a TEMPORARY DEFERRAL for 12 months following the event)

GROUP D:

1. Have you at any time since 1980 injected Bovine (Beef) Insulin?

(A "Yes" answer to Group D is an INDEFINITE DEFERRAL)

Direct Oral Questions January 10, 2010
Army Blood Program Policy Letter 2010-01-02

Enclosure 4, Rapid Test Worksheet

Rapid Testing Worksheet

Location:_____.

Date of Testing:_____.

Tech:_____.

	Rapid Tests																	
	HCV (Oraquick)			HBsAg (Onsite/CTK)			RPR (ASI/Cardinal)			Malaria Now			HIV (Oraquick)					
	Lot #:			Lot #:			Lot #:			Lot #:			Lot #:					
	Exp:			Exp:			Exp:			Exp:			Exp:					
Assigned Unit #	Sample results		IQC OK?	Sample results		IQC OK?	"SR" Strong Reactive	"WR" Weak Reactive	"NR" Non-Reactive	Sample results		IQC OK?	Sample results		IQC OK?			
POS EQC**	R	NR		R	NR					R	NR		R	NR				
NEG EQC**	R	NR		R	NR					R	NR		R	NR				
	R	NR		R	NR		SR	WR	NR	R	NR		R	NR				
	R	NR		R	NR		SR	WR	NR	R	NR		R	NR				
	R	NR		R	NR		SR	WR	NR	R	NR		R	NR				
	R	NR		R	NR		SR	WR	NR	R	NR		R	NR				
	R	NR		R	NR		SR	WR	NR	R	NR		R	NR				
	R	NR		R	NR		SR	WR	NR	R	NR		R	NR				
	R	NR		R	NR		SR	WR	NR	R	NR		R	NR				
	R	NR		R	NR		SR	WR	NR	R	NR		R	NR				
	R	NR		R	NR		SR	WR	NR	R	NR		R	NR				
	R	NR		R	NR		SR	WR	NR	R	NR		R	NR				
	R	NR		R	NR		SR	WR	NR	R	NR		R	NR				
	R	NR		R	NR		SR	WR	NR	R	NR		R	NR				
	R	NR		R	NR		SR	WR	NR	R	NR		R	NR				
	R	NR		R	NR		SR	WR	NR	R	NR		R	NR				
	R	NR		R	NR		SR	WR	NR	R	NR		R	NR				
	R	NR		R	NR		SR	WR	NR	R	NR		R	NR				
	R	NR		R	NR		SR	WR	NR	R	NR		R	NR				
	R	NR		R	NR		SR	WR	NR	R	NR		R	NR				
	R	NR		R	NR		SR	WR	NR	R	NR		R	NR				
	R	NR		R	NR		SR	WR	NR	R	NR		R	NR				
	R	NR		R	NR		SR	WR	NR	R	NR		R	NR				
	R	NR		R	NR		SR	WR	NR	R	NR		R	NR				
	R	NR		R	NR		SR	WR	NR	R	NR		R	NR				
	R	NR		R	NR		SR	WR	NR	R	NR		R	NR				
	R	NR		R	NR		SR	WR	NR	R	NR		R	NR				
	R	NR		R	NR		SR	WR	NR	R	NR		R	NR				
	R	NR		R	NR		SR	WR	NR	R	NR		R	NR				
	R	NR		R	NR		SR	WR	NR	R	NR		R	NR				
	R	NR		R	NR		SR	WR	NR	R	NR		R	NR				
	R	NR		R	NR		SR	WR	NR	R	NR		R	NR				
	R	NR		R	NR		SR	WR	NR	R	NR		R	NR				
	R	NR		R	NR		SR	WR	NR	R	NR		R	NR				
	R	NR		R	NR		SR	WR	NR	R	NR		R	NR				
	R	NR		R	NR		SR	WR	NR	R	NR		R	NR				

** If available

√=Acceptable

R= Reactive

NR= Non-Reactive

Technical Review: _____ Date: _____

QA/QC Review: _____ Date: _____

Form 145 (FOB version)
V: 09 Sep 2010

Enclosure 5, Donor Sample Submission Requirements (dtd 10 Sep 2010)

Official Copy

1. **General Information:**

Robertson Blood Center (RBC) provides management and tracking of donor samples for testing for deployed units as directed and approved by the Army Blood Program Manager, U.S. Army Medical Command (MEDCOM). The goal of RBC is to ensure the quality of samples and test results in a timely manner.

2. **Laboratory Address/Phone Numbers and E-mail Addresses:**

Robertson Blood Center
Building 2250, 761st Tank Battalion Ave
Fort Hood, TX 76544

Telephone numbers are listed below:

RBC Secretary	(254) 287-7113 (DSN 737)
Technical Supervisor	(254) 287-3989 (DSN 737)
Director	(254) 287-8132 (DSN 737)
Deputy Director	(254) 618-8896 (DSN 259)
QA	(254) 288-6404 (DSN 738)
	(254) 288-9457 (DSN 738)
NCOIC	(254) 618-8744 (DSN 259)
On-Call Tech	(254) 535-2829
FAX Number	(254) 288-6405 (DSN 738)

E-mail addresses are listed below:

michelle.gutierrez@amedd.army.mil
lizabeth.nieves@amedd.army.mil
steven.mcdaniel@amedd.army.mil
dennis.dombrowski@amedd.army.mil

3. **Laboratory Hours:**

RBC Staff is available Monday through Friday from 0730 to 1630 Central Standard Time (CST), except federal holidays. The On-Call Tech is available 24/7 at the telephone number provided.

4. **Collection and Submission of Specimens:**

RBC Form 145
September 10, 2010

Official Copy

Robertson Blood Center Specimen Submission Guidelines

- Specimen Requirements: Peripheral blood, obtained through sterile venipuncture, is the recommended specimen for all tests. Submit the following for each whole blood/plateletpheresis donor:
  a. One (1) EDTA tube, ISBT barcode-labeled that contains at least 3 mL of sample for processing at BSD.
  b. Three (3) plastic Nalgene tubes for processing at RBC, each containing at least:
     1. 3 mL PLASMA
     2. 3 mL PLASMA
     3. 3 mL SERUM
  c. Each of the 3 Nalgene tubes is:
     1. Capped then parafilmed
     2. Properly affixed with an ISBT barcode label
     3. Labeled as either a "PLASMA" or "SERUM" specimen

- Each specimen must be labeled properly with an ISBT- barcoded unit number. **PLACEMENT OF THE ISBT LABEL IS CRITICAL FOR POSITIVE DONOR IDENTIFICATION.** ISBT labels must be affixed so that they are parallel to the axis of the tube (up and down, not wrapped around). When using the ISBT labels, the small barcodes should be placed lengthwise near the top of the tube. If the large ISBT labels must be used, place the label lengthwise and, as close to the top of the tube as possible.

- Each specimen must be centrifuged at the calibrated time, speed and temperature specified in the BSD facility SOP prior to aliquoting into Nalgene tubes.

- Serum and plasma must be separated from the cells within 3 days of collection.

- Specimens may be kept refrigerated in the original container for up to 7 days at 2-8C. In order to retain the specimen after the 7th day, the serum or plasma must be stored frozen at -20C or colder. Specimens should be frozen as soon as possible.

- All specimens will be submitted through the theater BSD to the Robertson Blood Center.

- The BSD will notify RBC by e-mail when shipping specimens for testing. Please include the date of shipment, shipping tracking number and number of specimens.

- Accompanying Documentation: Submit a manifest of all specimens to be tested, in numerical order. RBC will notify the submitting BSD when the specimens do not match the manifest.

- Mislabeled, unlabeled, grossly hemolyzed or leaking specimens will not be processed. Specimens contaminated by another leaking specimen will not be processed. RBC will notify the submitting BSD of the problem.

RBC Form 145
September 10, 2010

3

- If insufficient specimen is received, the unit ID will be annotated as "QNS" and partial results may be reported. **When additional sample is submitted, please indicate which test(s) is/are still required.**

5. **Safe Specimen Procurement, Transport, and Handling:**

- Specimens should be shipped in sample transport trays or racks and listed on the accompanying documentation (in the same order). If transport trays or racks are unavailable, specimens bearing the same unit number will be bound together using a rubber band.
- Specimens should be wrapped in suitable absorbent packing material to insulate and secure then placed in a leak-proof plastic bag and sealed.
- Place the leak-proof bag in the center bottom of a Collins box.
- Fill the Collins box with dry ice to ensure that the shipment is received frozen.
- All accompanying documentation must be attached to the inside lid of the box.
- Ship specimens according to all applicable federal, state, and operator regulations. In general, follow recommendations outlined by the International Air Transport Association (IATA) and 49 CFR (DOT) manuals for the shipment of Diagnostic Specimens. Personnel handling samples for transport should be trained in safe handling practices and decontamination procedures in case of spill. **Ensure that all requirements for shipping with dry ice are met.**

6. **Specimen Retention:**

- RBC will not maintain a frozen provial specimen on any unit. Maintenance of a provial sample will be the responsibility of the submitting BSD.

7. **Reporting Results:**

- RBC will forward testing result via e-mail to the submitting BSD as soon as test results have been reviewed.
- Both the BSD and Robertson Blood Center will maintain records for historical purposes.

Official Copy

Robertson Blood Center Specimen Submission Guidelines

- See Creative Testing Solution's Tests and Results Legend below:

Report Text	Description
HBC	HBc Antibody
HBSA	Hepatitis B Surface Antigen
HCV	Hepatitis C Antibody
HIV	HIV-1/HIV-2 Plus O EIA
HTLV	HTLV I/II EIA Antibody
IAT	Indirect Antiglobulin Test
NAT	HIV-1/HCV/HBV NAT Ultrio Test
STS	Serological Test for Syphilis
WNV	West Nile Virus NAT Test
NT/UND	Not Tested
N/NR/NEG	Negative/Nonreactive
R	Positive/Reactive
P/POS	Positive
X	No Test Result

RBC Form 145 5
September 10, 2010

Enclosure 6, Equipment and Materials List with NSN

ITEM DESCRIPTION	STOCK# / NSN #
SHARPS Container	6515014922824
Biohazard Bags	0707A950012
Trash Bags	8105011839767
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)	6550015119294
HIV 1/2 RA OraQuick	6550015267424
ORAQUIK HCV	6550015899845
ONSITE (CTK) HBSAG (Hep B)	6550008T000102
Malarial Rapid Test	6550081332341
RPR	6550015110291

APPENDIX C

ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGs

A. 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.

B. 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.

C. 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.

D. 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.