APPENDIX C: EMERGENCY WHOLE BLOOD COLLECTION SOP

Emergency Whole Blood Collection Standard Operating Procedures

Purpose: This Standard Operating Procedure (SOP) accompanies the Whole Blood Transfusion Clinical Practice Guideline published by the Joint Trauma System, the DoD Center of Excellence for Trauma.

1.0 Materials and Equipment

Use the following materials and equipment as applicable

- Vitals Machine
- Blood Collection Beds
- Stethoscope
- Blood Pressure cuff
- Digital Thermometer and/or Tempadots
- Lancets
- POCT Hemoglobinometer
- Electronic table top scale (optional)
- Alcohol Pads
- Coban
- Blood Bags (CPDA-1 or CPD)

  ***NOTE**: If an additive solution (AS) bag is present with a multiple bag set-up, the AS SHALL NOT be added to the whole blood.*
- Blood Trip Scale with 585±2g trip counter-weight and QC weights or HemoFlow.
- Testing Collection Set: premade bags with sterile 4x4 gauze, Chloraprep, 2 red top tubes, 4 purple top tubes

  ***NOTE**: Gold/yellow top (serum separator) tubes may be substituted for red top tubes.*

  Note: Pearl top (plasma preparation) tubes may be substituted for 3 of the purple top tubes.
- ChloraPrep
- Adapter Luer
- ABO/Rh Testing Card (e.g., Eldon Military Kit or other FDA-approved device)
- 4x4 Gauze
- Adhesive Tape
- Hemostats
- Gloves
- Tourniquet
- Rapid HIV, Malaria, HBsAg, and HCV test kits
- Serological RPR kit
- Plastic Aliquot tubes/lids
- Parafilm
- Clinical Rotator
- Centrifuge
- Disposable Pipettes
- Scissors
- Strippers
- Metal Clips
- Biohazard Container/ Sharps Container
- Whole Blood ISBT Labels (100 number series)

OR

- **Fresh Whole Blood Collection Set**

(Donor & Recipient Modules) contains all items above (or alternatives), other than those shaded gray

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2.0 Records/Forms

- Forms required:
- Modified ASBP 572-EWB
- Form 145
- Form 147
- Form 148
- Form 150A
- Form 150B
- Form 151 and SF 518 (as applicable)
- Theater Medical Data Store (TMDS)
- Blood Portal

3.0 Quality Control (QC)

- Perform QC on POCT Hemoglobinometer
- Perform QC on ABO/Rh Testing Card, RPR, HCV, HBsAg, HIV, and Malaria Kits (See package inserts and local SOPs for procedures.)
- Medical personnel should be trained by blood donor center/Blood Support Detachment or other qualified personnel.

4.0 Procedures

Perform the following steps when a physician requests whole blood units:

1. Permission to Conduct the Blood Drives

- Notify Role 2/3 Commander, DCCS and Laboratory OIC/NCOIC that a physician is requesting whole blood for transfusion.
- Once the Commander/DCCS/Medical OIC grants permission, initiate the emergency whole blood collection. Notify the Area Joint Blood Program Officer that facility is performing whole blood collection. Trained medical personnel should oversee the process.

2. Donor Recruitment

- When emergency whole blood collections are required, donors will be selected in the following order, in descending priority:

  a. Donors who have been prescreened within the last 90 days with the full panel of FDA-licensed donor infectious disease tests and found to be negative for all tests.
  NOTE: *Any donor with a positive test result will not be listed as an approved, prescreened donor and must not be collected.*

  b. Donors who have been prescreened between 90 days and 365 days with the full panel of FDA-licensed donor infectious disease tests and found to be negative for all tests.

  c. Donors who report being repeat blood doors in the past and have not been deferred for transfusion-transmitted disease.

  d. Donors who have not been prescreened with FDA-licensed tests, nor have been blood donors in the past.

- To the maximum extent possible:

  a. Blood will only be collected from United States personnel to include military members, DoD civilians or contractors, or beneficiaries.

  b. Blood may be collected from pre-screened coalition partner forces if screening program has been reviewed by the JBPO and deemed acceptable by the COCOM Surgeon and the ASBP. Note, screening results must be available to the JBPO.

  c. On the day of donation, prospective donors will be screened for eligibility using approved donor history screening protocols and be tested for infectious diseases using ASBP-approved rapid screening tests. As much as possible, rapid screening tests should be performed before issuing the product.

- Low titer Group O Whole Blood (LTOWB) donors have been tested and found to have anti-A/anti-B antibody titers of <1:256 (recorded in TMDS). LTOWB collected from these donors may be given to a recipient of any ABO type during damage control resuscitation.

- Non-LTOWB FWB donors must be an ABO type-specific match to the casualty. If not matched, a fatal hemolytic reaction may occur. Casualty ABO/Rh type must be determined (by using rapid ABO/Rh card or laboratory testing) before conducting type-specific FWB collection.

3. **Pull a pre-screened donor list from TMDS: Manage Donor>View Donor List.**

4. **Select filters**

   a. Select filters for ABO/Rh of the potential whole blood recipient if using type-specific FWB, Screened (select ALL), Alert (select ALL), COCOM (select applicable).

   b. Highlight your facility in the Available Facilities tab and click Add.

   c. Once your facility appears in the Search Facility box, click Display Donor List.

   d. The potential donor list for the blood type required will now appear on the screen.

   ***NOTE**: If searching for LTOWB pre-screened donors, use same process above except select O pos and O neg in the ABO/Rh selection area.*

5. **Verify donor**

The donor ABO/Rh must be verified (by rapid ABO/Rh card or laboratory testing) prior to transfusion even if donor is in TMDS with pre-screening results.

5.0 Donor and Testing Area Preparation

1. Set up blood donor beds.
2. Perform QC on weighing device if available, (i.e., HemoFlow or Trip Scale).

   ***NOTE:** If no trip scale is available, see section below Whole Blood Collection: Set up the whole blood collection bag.*

3. Ensure the necessary equipment to perform donor screening, testing and collection are available. (See WBB Supply List with NSNs)

6.0 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 to the recipient of Transfusion Transmitted Diseases (TTD) and hemolytic reactions.
2. Give donor ASBP 572-EWB and instruct donor to complete demographic information and to answer questionnaire by circling "Yes" or "No". While donor is completing questionnaire, 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 ASBP 572-EWB for completeness and donor suitability criteria following steps below.

   If/Then Scenarios

   IF: Responses for questions 1 and 9 are "Yes" AND Responses for questions 2-8 and 10-26 are "No"*
   THEN: Proceed to step 5 for donor temperature.

   IF: Response to question 1 or 9 is "No" AND/OR There are any "Yes" responses for questions 2-8 or 10-26*
   THEN: Document the reason for the "Yes" response (questions 2-8 or 10-26) or "No" response (questions 1 or 9). Defer the donor.

   ***NOTE**: For question 13, if the donor is required by the Chain of Command to take malaria prophylaxis due to deployed location, then response should be "Yes". If donor answers "No" despite being required to take prophylaxis, then donor should be deferred unless all other suitable donors are unavailable.*

5. Perform and record temperature on the ASBP 572-EWB.

   If/Then Scenarios

   IF: ≤99.5 ºF or 37.5 ºC
   Then: Proceed to the next step.
   IF: >99.5 ºF or 37.5 ºC
   Then Stop the donation process. The donor is "Ineligible" at this time.

6. Perform and record measurements of donor pulse and blood pressure on the ASBP 572-EWB.

   IF: Systolic BP is 90-180
   Diastolic BP is 50-100
   Pulse is 50-100 bpm

   THEN: Proceed to step 7 for donor hematocrit.

IF: Systolic BP is <90 or >180
Diastolic BP is<50 or >100
Pulse is <50 or >100
THEN: Stop the donation process. The donor is "Ineligible" at this time.

7. Perform and record hematocrit/hemoglobin results on ASBP 572-EWB, if possible.

If/Then Scenarios

IF: Male: ≥13.0 g/dL
Female: ≥12.5 g/dL
THEN: Proceed to next step.

IF: Male: <13.0 g/dL
Female: <12.5 g/dL
THEN: Defer donor and stop the donation process. The donor is "Ineligible" at this time.

8. Donor is physiologically acceptable to donate, have the donor sign the ASBP 572-EWB and proceed to next step.

9. A competent medical authority should review the ASBP 572-EWB to determine the eligibility of the donor.

IF/Then Scenarios
IF: Acceptable.
THEN: Donor is "Eligible," proceed to Step 10.

IF: Unacceptable.
THEN: Donor is "Ineligible," stop donation process and document deferral as appropriate in TMDS.

10. Issue blood bag and test collection set to donor. Label bag and ASBP 572-EWB with Whole Blood ISBT labels. Blood collection tubes (2 red top 4 purple top) 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 DoD ID or Blood Bag Segment Number.

7.0 Whole Blood Collections

1. Seat donor in blood donor table or reclining chair. Ask the donor their name and verify donor demographic information is correct on the ASBP 572-EWB. Verify also that the labels on the blood bag, sample tubes, and ASBP 572-EWB correctly correspond to each other and the donor.

NOTE: *If a discrepancy is noted, STOP and correct before proceeding further.*

2. Apply the tourniquet to the arm that will be used for phlebotomy.
   - Have donor grip their hands or a squeezable object
   - Palpate the antecubital area of the arm in order to locate a suitable vein
   - Remove the tourniquet

Note: *The vein of choice must be large enough for venipuncture using a 16-gauge needle and straight enough to accommodate at least one-fourth of the needle length*

3. Utilizing ChloraPrep, remove applicator from package; do not touch applicator tip.
4. Holding sponge tip down, pinch barrel of applicator to release antiseptic and wet sponge tip by pressing and releasing the sponge against the treatment area until liquid is visible on the skin.
5. Use gentle back-and-forth strokes over the 3 inch treatment area for 30 seconds and then allow area to dry for 30 seconds. Do not blot or wipe away antiseptic.

   NOTE: *It is not necessary to use the entire amount of the solution in the applicator*
6. Set up the whole blood collection bag.

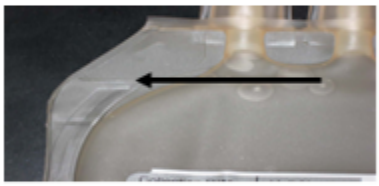
   - Ensure that the donor's ISBT Label or ID has been recorded in the Unit Number field on the CPD Whole Blood Collection bag if not previously performed.
   - Ensure date is recorded in the "Today's Date" field under the Group B questions.

   Inspect the bag and tubing for cuts, kinks, discoloration or any kind of damage and discard bag if present.
7. Set-up trip scale (Manual or Electronic). Perform quality control, if possible, to obtain a counter-weight of 585 grams.

   NOTE: *If no trip scale is available, the Terumo Single Blood Bag (CPDA-1) can be filled with whole blood to the mark pictured below. It is however recommended that weight then be checked with table top scale (if available)*

   The target weight for 450 mL is 585 grams.

   Do not use if overfilled as blood clots may develop from an incorrect ratio of whole blood to anti-coagulant causing potential harm to the patient.

   
8. Using a hemostat, clamp tubing between the needle and the main bag. This will prevent air contamination of blood after the needle cover is removed. Place tape within reach for anchoring the needle during phlebotomy.

   NOTE: *Place a loose knot in the tubing approximately 6 inches from the needle prior to uncapping needle, if metal seal clips and hand crimpers are not available.*
9. Apply tourniquet with enough pressure. If using a blood pressure cuff adjust to approximately 40-60 mm Hg.
10. Twist off the needle cover and inspect the needle for barbs or other defects.
11. Pull the skin taut below the venipuncture site.
12. 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.
13. 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.

14. Release the hemostat clamp on the collection bag tubing and observe the blood flow through the tubing and into the collection bag.

    IF/THEN Scenarios

    IF Blood flow is impeded
    THEN: Try adjusting the needle with least discomfort without hurting the donor.

    IF: Blood flow is still impeded
    THEN: Seek assistance from another phlebotomist before discontinuing the phlebotomy.

15. Fill sample tubes using tube adapter if available. 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 ASBP 572-EWB.

    NOTE: *If no tube adapter available on whole blood bag tubing, fill sample tubes by performing a venipuncture phlebotomy on the arm not used for whole blood bag donation.*

16. Instruct donor to relax their grip and to rhythmically squeeze every 5 to 10 seconds, relaxing between squeezes.

17. 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.

18. 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.

19. 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.

20. 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.

21. Record the following in the appropriate blocks on the ASBP 572-EWB:

    - Time phlebotomy was started
    - Initials of the phlebotomist

22. 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 ASBP 572-EWB.

    NOTE: *A 10 inch piece of 5-50 cord/nylon cord may be used to check for unit fill. As bag fills, place cord around middle/center of bag and continue to monitor until both ends of the cord wrap around the bag and touch.*

23. 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).

24. 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.
25. Remove tourniquet or blood pressure cuff and tape strips from donor's arm.
26. 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.
27. 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.
28. Secure the dressing with Coban or similar bandage wrap. Observe the donor for an appropriate length of time after the donation for any signs of an adverse event.
29. Discard the needle assembly into a sharps container.
30. 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)
31. 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.

8.0 Process Donor Units

1. Take donor unit and donor sample tubes (2 red top tubes, 4 purple top tubes) to processing area.
2. Strip donor units segment tubing three times and mix, so as to avoid the development of clots.
3. Perform ABO, Rh type utilizing ABO/Rh Testing Card and purple top tube. Record results on Form 147.
4. Write the donor blood type on the bag (ABO/Rh Testing Card) along with date, time and phlebotomist initials of collection.
5. If whole blood unit is drawn from a low titer donor, "Low Titer for Anti-A/Anti-B" should be written on the label or use a sticker with the same verbiage.
6. Write the expiration date of the unit on the label, which is 24 hours from collection if stored at room temperature. If placed into refrigerated storage within 8 hours of collection, the unit may be stored for 21 or 35 days depending on anticoagulant. JBPO approval is required for storage of whole blood unit for longer than 24 hours.

   NOTE: *CPDA-1 units have a 35 day expiration / CPD units have a 21 day expiration*
7. 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.*

9.0 Create Whole Blood Units in TMDS

1. From Manage Donation tab, select Donate Product.
2. Enter the Donor SSN, first name, last name in appropriate fields and click NEXT.
3. In Demographic information area, enter donor's ABO/Rh, nationality and branch. Military unit and contact instructions may also be entered in the demographic information fields. Enter donor's redeployment date if known along with further contact information. In the Donation information area, enter the pre-screen date, document status of ASBP 572-EWB completion, donor's ABO/Rh and Donor Identification Number (DIN). Click ADD PRODUCT(S).

   NOTE: *If any of the TMDS auto-populated information fields in demographic information area is incorrect, contact the JBPO or TMDS Help Desk for guidance. TMDS contact information can be found on the TMDS log-in screen.*

   NOTE: *The Donation Location field information will be auto-populated within TMDS.*
4. Enter product code E0053V00 for whole blood collected in CPDA-1 anticoagulant or E0009V00 for whole blood collected in CPD anticoagulant.
5. Enter the expiration date of the unit, which is 24 hours from collection if stored at room temperature. If placed into refrigerated storage within 8 hours of collection, the unit may be stored for 21 or 35 days depending on anticoagulant. JBPO approval is required for storage of whole blood unit for longer than 24 hours.

   NOTE: *CPDA-1 units have a 35 day expiration / CPD units have a 21 day expiration*
6. Click Add Product.
7. Verify donation ID, product description, product type, ABO/Rh and expiration date are correct, then click NEXT.
8. Re-verify all demographic and unit data then click Confirm Donation.
9. Repeat steps 1-8 for each product collected.

10.0 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. Centrifuge 2 Red Top and 3 Purple Top Tubes for 5 minutes at 4000 RPM.
3. Perform Rapid ABO/Rh using whole blood from 4th purple top tube and record results on Form 147.
4. Perform HBsAg, HCV, HIV, and Malaria using whole blood from 4th purple top tube. Perform RPR using serum from centrifuged red top tube. Testing should be performed IAW Test Kit package inserts and local SOP. Record reagent Name, Lot #, Exp Date, and Results on Form 145.
5. Upon completion of rapid tests with negative results, whole blood unit may be issued for transfusion.

6. When time allows, rapid test results need to be entered into TMDS. To do this click on Update Donation under the Manage Donation tab.

11.0 Issue and Manage 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.

12.0 Process Samples for Shipment and Testing

1. Label three aliquot (pour off) tubes with corresponding ISBT Labels with small barcodes. Position the ISBT label vertically toward the top of tube. Write "Serum" on one tube and "Plasma" on the other two tubes. If ISBT labels are not available utilize the Donor's DoD ID or other unique identifier as appropriate to label the pour off tubes.
2. Place plasma from 3 Purple Top tubes into the 2 aliquot tubes labeled "Plasma". *3ml sample requirement per aliquot.
3. Place serum from 2 Red Top tubes into the 1 aliquot tube marked as "Serum".

   Do not fill over ¾ full to allow for expansion from freezing
4. The seal of capped aliquot tubes should be reinforced with para-film wrap and placed into a biohazard shipping bag or rack. Repeat for each series
5. Record sample and donor demographic data on Form 148 (Shipping Manifest). Include a printed copy of manifest with shipment and e-mail to BSD or designated facility, if possible.
6. Form 151- Whole Blood Transfusion Checklist must be submitted with shipment for every unit of whole blood transfused.
7. Send copies of ASBP 572-EWB for each unit collection along with Form 145, Form 147 and Form 148 in a blood box (Collins Blood Box) with ice bag(s) to your respective blood detachment or designated receiving facility. E-mail a copy of manifest to BSD or designated facility, if possible, and call to alert about incoming shipment. Ensure originals of all forms remain at collecting location.
8. **Samples may be** frozen until they can be shipped to a designated laboratory to perform FDA-approved testing. Contact COCOM Joint Blood Program Office (JBPO) for guidance on specimen acceptability requirements. Depending on collecting unit/facility location and prior coordination, it may be possible to ship specimens directly to a testing or processing facility without performing the tube centrifugation and sample pour offs. Prior coordination MUST be made with COCOM JBPO or testing facility to ensure samples will remain viable if centrifugation step above will be skipped.
9. All donor tubes MUST be centrifuged and serum/plasma removed from RBCs within 72 hours of collection. The BSD or designated unit/facility will send all samples to designated laboratory for

FDA-approved testing. BSD or designated facility will enter results in TMDS and forward to submitting Role 2 or Role 3 upon completion. In some cases, the submitting Role 2 or Role 3 may have to enter results into TMDS if not supported by a BSD.

NOTE: *Testing for group O donors may include anti-A and anti-B titer testing. The titer testing must be coordinated with the testing facility prior to sample shipment.*

NOTE: *The results of this testing will be viewed as a pre-screen for donor's next donation.*

10. Any positive testing that is received by BSD or unit will be forwarded to Preventive Medicine Consultant or available Provider (MD, DO, PA, NP) to ensure proper donor care and follow-up is initiated. At no time will laboratory staff notify donors directly regarding positive testing results. JBPO will be notified of positive results to ensure recipient notification is completed for transfused units.

13.0 References

- AABB Technical Manual, current edition
- AABB Standards for Blood Banks and Transfusion Services, current edition.
- JTS Clinical Practice Guideline: Fresh Whole Blood (FWB) Transfusion
- Theater Medical Data Store (TMDS) System User's Manual, current edition.

14.0 Enclosures

- Form 145-A Rapid Testing Worksheet
- Form 150A–Emergency Release Letter of Understanding (tested)
- Form 150B–Emergency Release Letter of Understanding (un-tested)
- Form 151–Whole Blood Transfusion Checklist
- Standard Form 518-Blood or Blood Component Release
- WBB Supply List (with NSNs)

~END~

EMERGENCY WHOLE BLOOD COLLECTION SOP ENCLOSURES (1)

Form 145: Rapid Testing Worksheet

Date:_________
Tech:_________

Disease Rapid Testing

	Rapid Tests												RPR	
	Malaria			HIV 1/2			HCV			HBsAg			Rotator (100 +/- 5 rpm):100	
	Lot #:			Lot #:			Lot #:			Lot #:			Lot #:	
	Exp:			Exp:			Exp:			Exp:			Exp:	
Assigned Unit #	Sample results		IQC OK?	Sample results		IQC OK?	Sample results		IQC OK?	Sample results		IQC OK?	"R" Reactive	"NR" Non-Reactive
	R	NR		R	NR		R	NR		R	NR		R	NR
	R	NR		R	NR		R	NR		R	NR		R	NR
	R	NR		R	NR		R	NR		R	NR		R	NR
	R	NR		R	NR		R	NR		R	NR		R	NR
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	R	NR		R	NR		R	NR		R	NR		R	NR
	R	NR		R	NR		R	NR		R	NR		R	NR
	R	NR		R	NR		R	NR		R	NR		R	NR

Supervisor Review: ________________ Date: _______________

QA/QC Review: ________________ Date: _______________

Form 145
V: 07 Sep 2015

EMERGENCY WHOLE BLOOD COLLECTION SOP ENCLOSURES (2)

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

EMERGENCY WHOLE BLOOD COLLECTION SOP ENCLOSURES (3)

Form 150B: Emergency Release Letter of Understanding (Untested)

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

EMERGENCY WHOLE BLOOD COLLECTION SOP ENCLOSURES (4)

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

EMERGENCY WHOLE BLOOD COLLECTION SOP ENCLOSURES (5)

Standard Form 518-123: Blood or Blood Component Release

518-123 NSN 7540-00-634-4158

MEDICAL RECORD | **BLOOD OR BLOOD COMPONENT TRANSFUSION**

SECTION I - REQUISITION

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

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

DATE REQUESTED

DATE AND HOUR REQUIRED

REQUESTING PHYSICIAN *(Print)*

DIAGNOSIS OR OPERATIVE PROCEDURE

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

VOLUME REQUESTED *(If applicable)*
_____ ML

KNOWN ANTIBODY FORMATION/TRANSFUSION REACTION *(Specify)*

SIGNATURE OF VERIFIER

REMARKS:

IF PATIENT IS FEMALE, IS THERE HISTORY OF:
RhIG TREATMENT? DATE GIVEN: _____
HEMOLYTIC DISEASE OF NEWBORN? _____

DATE VERIFIED

TIME VERIFIED

SECTION II - PRE-TRANSFUSION TESTING

UNIT NO.	TRANSFUSION NO. / PATIENT NO.	TEST INTERPRETATION: ANTIBODY SCREEN	TEST INTERPRETATION: CROSSMATCH
DONOR	RECIPIENT		
ABO	ABO		
Rh	Rh		

PREVIOUS RECORD CHECK: ☐ RECORD ☐ NO RECORD

SIGNATURE OR PERSON PERFORMING TEST

☐ CROSSMATCH NOT REQUIRED FOR THE COMPONENT REQUESTED | DATE

REMARKS:

SECTION III - RECORD OF TRANSFUSION

PRE-TRANSFUSION DATA

INSPECTED AND ISSUED BY *(Signature)*

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

IDENTIFICATION

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

1st VERIFIER *(Signature)*

2nd VERIFIER *(Signature)*

PRE-TRANSFUSION
TEMP. | PULSE | BP

DATE OF TRANSFUSION | TIME STARTED

POST-TRANSFUSION DATA

AMOUNT GIVEN | TIME/DATE COMPLETED/INTERRUPTED

REACTION ☐ NONE ☐ SUSPECTED | TEMPERATURE | PULSE | BLOOD PRESSURE

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

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

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

SIGNATURE OF PERSON NOTING ABOVE

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

BLOOD OR BLOOD COMPONENT TRANSFUSION
Medical Record

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

Standard Form 518-123: Blood or Blood Component Release (instructions)

INSTRUCTIONS FOR NON SELF-EXPLANATORY ITEMS

SECTION I – REQUISITION

Component Requested

"Other (Specify)" – List any whole blood or blood product not on menu, i.e., washed RBC's deglycerolized RBC's, etc.

"Volume Requested (If applicable)" – Use only when different from standard amount, i.e., exchange transfusion 50 ml.

"Known Antibody Formation/Transfusion Reaction" – Check Medical Records. Annotate N/A if appropriate.

"If Patient is Female, Is There History Of" – Check medical records. Annotate N/A if appropriate.

SECTION II – PRE-TRANSFUSION TESTING

"Transfusion Number/Patient Number" – List either based on local procedures.

"Previous Record Check" – Current tests should be compared with prior records for ABO and Rh type, difficulty in blood typing, clinically significant unexpected antibodies, and severe adverse reactions.

"Test Interpretation" – Use the following standard notations. "NEG or "POS" for antibody screen block. "COMPAT" or "INCOMPAT" for crossmatch block.

SECTION III – RECORD OF TRANSFUSION

"Pre-Transfusion Data"

"Inspected and Issued by _____ at _____ on _____."
(Signature) (Hour) (Date)

This statement is to be completed by the issuing laboratory person once he/she has inspected the blood immediately before issue from the laboratory. The blood must not be abnormal in color or appearance or expired, and if any of these conditions exist the blood will not be used for transfusion.

"Signature" blank must contain the signature, as opposed to name, of issuing laboratory person.

"Hour" and "Date" are as of actual issue.

The issuing laboratory person will secure this form to the blood bag by string, rubberband, or tie knotted to the tag and the blood container before issuing the blood.

"Post-Transfusion Data" – Completed by transfusionist.

"Amount Given _____ ml" – Visual approximation.

"Description of Reaction" – Check appropriate reaction or describe "other" on separate sheet, if necessary, and attach to SF 518.

"Other Difficulties"– Check item or describe on separate sheet and attach to SF 518.

STANDARD FORM 518 BACK (REV. 9-92)

EMERGENCY WHOLE BLOOD COLLECTION SOP ENCLOSURES (6)

WBB and Pre-screen Supply List

WBB and Pre-Screen Supply List

Item	NSN
Fresh Whole Blood Collection Kit	6515-01-657-4750
Fresh Whole Blood Donor Set	6515-01-664-0306
Fresh Whole Blood Recipient Set	6515-01-663-9469
Purple top tubes	6640-01-378-0086
Gold top tubes	6640-01-585-5768
Pearl top tubes	6640-01-573-5282
Transfer Pipettes	6640-01-088-4246
Eldon Cards	6550-01-587-1889
Transfer pipettes	6640-01-088-4246
Malaria	6550-01-554-8731
HCV	6550-01-589-9845
HIV	6550-01-526-7424
HBsAg	6550-01-658-8877
RPR	6550-00-159-5011
Plastic tubes	6640-08-133-0372
Para film	6515-01-509-2783
Tape	6510-00-926-8882
Terumo Single Blood Bags	6515-01-480-2307
Chloraprep	6510-01-551-3496
Coban	6510-01-156-2366
Hand Stripper/Sealer/Cutter	6515-01-140-5267
Hand Sealer Clips	6515-01-070-1532
Scissors	6515-00-365-0640
Lancets	6515-01-367-8980
Sphygmomanometer	6515-01-039-4884
Stethescope	6515-00-935-4008
Blood Scale Hemoflow (optional)	6515-12-513-7010
Scale Stand (Optional)	6515-00-411-4375