Wake Forest Baptist Medical Center	**Investigation of Suspected Adverse Reactions to Transfusion** **BB.Routine.1010.4**	**Dept:**	**324311**
		Dept Name	**Blood Bank**
		Effective Date:	
		Revised Date:	
Name & Title: CLIA Laboratory Medical Director		**Contact:**	**JH Simmons/ CS Warren**
Signature: G Pompeu		**Date:**	2/11/2020

1. General Procedure Statement:

A. Purpose:

The Blood Bank will investigate all reported suspected transfusion reactions experienced by a patient in association with transfusion of blood and/or blood products including blood crossmatched and products dispensed by Wake Forest Baptist Blood Bank and sent to other associated facilities. The investigation includes: 1) reactions reported to the Blood Bank, 2) delayed reactions due to the formation of antibody following transfusion and 3) if the wrong patient and/or wrong product was transfused.

Blood transfusion may result in an adverse event. Any adverse event experienced by a patient in association with a transfusion shall be regarded as a suspected transfusion complication. All suspected transfusion complications shall be evaluated promptly, and reviewed by the medical director.

B. Responsible Department/Scope:

i. Procedure owner/Implementer: Julie H. Simmons/ Christina S. Warren
ii. Procedure prepared by: Julie H. Simmons
iii Who performs protocol: Department staff/management

C. Definitions:

Adverse Reactions	Adverse reaction due to a blood product transfusion
Acute Hemolytic	Acute hemolysis due to red cell incompatibility
Febrile, non hemolytic	Non hemolytic, due to accumulated cytokines and/or antibody to donor white cells
Urticarial	Simple localized/allergic reaction due to Antibody to donor plasma proteins
Anaphylactic	Severe reaction due to anti-IgA antibody to donor plasma proteins
TRALI	Transfusion-related acute lung injury due to WBC antibodies and or other WBC-activating agents in components
Transfusion associated sepsis	Severe reaction due to bacterial contamination
Circulatory Overload (TACO)	Transfusion Associated Circulatory Overload; Volume overload
Delayed Hemolytic	Anamnestic immune response to red cell antigens. Direct Antiglobulin Test positive. Antibody eluted from cells
PTP	Post transfusion purpura due to recipient platelet antibodies that destroy autologous platelets
Non-immunologic	Adverse reaction due to improper handling or administration of blood products. (Overheating of red cells, freezing of red cells, improper infusion solution used, etc.)
Market withdrawals / Look backs	Investigation initiated by blood supplier due to potential donor issue.
TRX1	Transfusion Reaction work-up routine
TRX2	Additional testing performed for Transfusion Reaction work-up if hemolytic

D. Sections: NA

E. Adverse Reactions to Transfusion Protocols

1.0 It is the protocol of the Wake Forest Baptist Health (WFBH) Blood Bank to investigate all reported suspected transfusion reactions experienced by a patient in association with transfusion of blood and/or blood products. This includes blood crossmatched and/or products prepared by WFBH and sent to other facilities or blood transfused by Air Care and EMS Ground.

2.0 The responsible patient's physician will determine that a transfusion reaction has occurred.

3.0 Blood and urine samples will be collected and submitted to the Blood Bank with the unit(s) transfused for the transfusion reaction work-up of all suspected transfusion reactions with the exception of simple localized urticarial (hives) reactions as determined by the responsible physician.

4.0 The pathology resident and/or medical director should be paged as soon as a transfusion reaction is reported to the Blood Bank so that they can check on the clinical status of the patient.

5.0 Notification of the pathology resident or medical director should occur before testing is started and the notification should be documented on the Suspected Adverse Transfusion Reaction Investigation Part II form including the name of the person notified.

6.0 The medical director or pathology resident MUST approve the issue of additional products after the reaction work-up has been completed and should be contacted if products are requested before this occurs.

7.0 All reported transfusion reactions will be recorded in the Transfusion Reaction Log Book with patient name, medical record number, donor number/component involved, time of reaction, time reported to Blood Bank, time pathologist called, time additional blood products are made available, results of Gram stain and culture report if applicable, and Medical Director comments.

8.0 The pathology resident will evaluate the initial results and obtain clinical information as needed. They will document their findings in WakeOne.

8.1 The pathology resident will consult with the patient's physician and medical director and order additional testing as needed.

9.0 The pathology resident will complete the Blood Utilization Review Form.

10.0 Interpretation of the evaluation shall be recorded in the patient's medical record and communicated to the patient's physician for all reported reactions including; but, not limited to, hemolytic reaction, bacterial contamination, TRALI, or other serious complication of transfusion.

11.0 Cancel any tests that are not performed to avoid billing the patient. Do not use "Not Tested" or "Not Done".

12.0 Urticarial (hives) and allergic mild reactions (itching, rash, pruritus, hives)

12.1 Mild reactions (allergic/urticarial) need NOT be evaluated as possible hemolytic reactions.

12.2 It will be evaluated based on the responsible physician's determination that the reaction is a simple localized urticarial (hives) and the patient is stable.

12.3 Simple localized urticarial reactions do NOT require that a blood or urine specimen be sent to the Blood Bank. The transfusionist should indicate that a transfusion reaction has occurred by checking "yes" on the transfusion unit tag, marking urticarial on the unit tag and writing "no specimens collected" on the unit tag.

a. If 'No Specimen collected' is not written on the transfusion unit tag, then Blood Bank staff may record it on the transfusion product tag to document.

b. For Simple Localized Urticarial Reactions:

IF	DO
NO blood or urine samples are sent to Blood Bank and/or only the blood bag is received	a. Order Transfusion Reaction in Beaker and accept into SCC (TRX1). b. Page or call pathology resident and ask if a transfusion work-up is needed. c. Pathology resident will determine within an hour if a work-up is needed, notify Blood Bank AND notify the floor to send specimens. d. Pathology Resident or Medical Director will write the WakeOne note. e. Record in the Transfusion Reaction Log Book. f. Tests that are not completed will be cancelled in SCC.
Blood and Urine samples are sent to Blood Bank with a simple localized urticarial reaction indicated	a. Order Transfusion Reaction in Beaker and accept into SCC (TRX1). b. Page or call pathology resident and ask if a transfusion work-up is needed. c. Pathology resident will determine within an hour if a work-up is needed and notify Blood Bank. d. Pathology Resident or Medical Director will write the WakeOne note. e. Record in the Transfusion Reaction Log Book. f. Tests that are not completed will be cancelled in SCC.

13.0 In SCC the special message: TRXI must be added to the patient's Patient Caution Window to indicate that a Transfusion Reaction is in process and units have not been approved for Issue without emergency release.

14.0 Do not issue any part or split of the product under Adverse investigation without approval of Medical Director. Quarantine all parts and splits until the Adverse investigation is completed. Review the release of splits and parts with the Medical Director.

15.0 All suspected transfusion complications are considered a STAT procedure and are to be acted upon immediately.

15.1 The pathology resident will notify the patient's physician and blood bank medical director.

15.2 The reaction should be signed off by the medical director/designee on the next business day after the suspected reaction has been reported.

16.0 Blood Bank Staff will notify Medical Director or Pathology Resident (when Medical Director is not available) by phone or web page. This notification will be RECORDED on transfusion reaction form.

16.1 Response by Pathology Resident is required. If no response, notify Pathologist on call.

17.0 Adverse Transfusion Reaction Forms

17.1 Part I of the transfusion reaction is completion of the lower section of the transfusion product tag indicating a suspected transfusion reaction.

17.2 Part II (Suspected Adverse Transfusion Reaction Investigation Part II) is the routine document for investigation of adverse reactions and is routinely used to document time pathologist notified and is also used during downtime.

17.3 Part III (Hemolytic Work-up form) is initiated if an acute hemolytic reaction is suspected.

17.4 The Blood Utilization Review form will be completed by the Medical Director or Pathology Resident.

17.5 Part II and Part III are used to document testing during downtime.

a. Once the computer system is back up, the information contained on the forms will be entered into SCC.

18.0 Unit bags must be saved for 7 days following the reaction. Units must not have any needles on tubing and unit should be placed in a plastic bag and labeled with the discard date.

19.0 The post reaction sample should be labeled "post reaction" and stored in the appropriate specimen rack (day of reaction).

20.0 Culture results

20.1 Keep transfusion reaction documents in Pathology completed letter file when culture results are pending.

20.2 Completed culture results:

a. Negative or no growth results is documented in Adverse Transfusion Reaction log.

b. Reported on Part II Suspected Adverse Transfusion Reaction Investigation form when it is initiated. Exception: When SCC printout of Adverse Reaction is the only report generated.

20.3 All positive culture results are submitted to Medical Director immediately for additional review.

21.0 All paperwork is reviewed by the manager/designee for completeness.

22.0 Manager/designee records the pathologist interpretation of the transfusion reaction in the Transfusion Reaction Log, enters the interpretation into SCC, and verifies that the Transfusion Reaction log entry is complete.

23.0 The Blood Utilization Review form is placed in the Blood Utilization Review notebook.

a. These are kept in the notebook for approximately 1 year.

b. Greater than one (1) year forms are filed in the irradiator room and kept indefinitely.

24.0 A physical copy of the completed adverse transfusion reaction documents is made.

a. The work-up may include one or more of the following forms:

1) Transfusion product tag

2) Suspected Adverse Transfusion Reaction Investigation Part II

3) Hemolytic work-up Part III

4) SCC Adverse Transfusion Reaction Report) is made

25.0 The original completed adverse transfusion reaction document will be sent via interoffice mail to Medical Records.

26.0 The physical copy of the adverse transfusion reaction will be filed alphabetically in the Adverse Transfusion Reaction file located in the Irradiator Room.

27.0 Transfusion Reactions will be scanned internally by Blood Bank or sent to an external company (currently Archive Information Management) so that the report can be maintained electronically.

27.1 All scans must be verified per procedure.

27.2 The scanned verified copy will be available in the Scanned Documents folder (Lab_Shared/BloodBankStaff/Scanned Documents/Adverse Transfusion Reactions).

28.0 Delayed hemolytic reactions may be suspected in the presence of a newly identified clinically significant antibody in a patient transfused within the previous three months. These reactions will be initiated by Blood Bank Technologist. Notify Pathology Resident to investigate and speak with patient's clinicians and place note in Wake One.

Refer to Attachment 1: Suspected Hemolytic Reactions, Immunologic

29.0 Blood Suppliers are required to report potential problems with blood products to the transfusion facility. These look backs and/or recalls are investigated by the Medical Director. Potential blood product issues identified by the Blood Bank will be appropriately reported to the blood supplier.

Refer to Quality Plan: Deviations, Nonconformances and Adverse Events.
Refer to Special Procedures: General Guidelines for Lookbacks

30.0 Reporting fatalities is the responsibility of the medical director and section manager. The medical director is also responsible for notifying risk management and other departments and personnel as needed.

Refer to Quality Plan: Deviations, Nonconformance and Adverse Events.

30.1 When a complication of transfusion is confirmed to be fatal, the Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research (CBER), shall be notified by phone, fax, mail or electronically as soon as possible but within 24 hours; a written report of the investigation shall be submitted within 7 days after the fatality per CFR title 21, part 606.1710(b) 2001.

Refer to QP: Errors: Errors and Accidents

30.2 The collecting facility shall be notified immediately and subsequently in writing, when a suspected transfusion fatality or other serious unexpected complication occurs and is suspected to be due to an attribute of the donor or a unit of blood or component.

31.0 A negative Direct Antiglobulin Test (DAT) does not rule out acute hemolysis if all transfused cells have been destroyed. The pathology resident will review the clinical picture and may request additional tests including the antibody screen on the post transfusion sample in these cases.

32.0 Blood suppliers provide plasma and whole blood for allogeneic transfusion from males, females who have not been pregnant or females that test negative for HLA antibodies to mitigate the risk for TRALI.

33.0 The following protocols reflect current CAP and AABB Standards.

Refer to *Attachment 6: Adverse Reactions- CAP and AABB Standards.*

2. Procedure: Transfusion Reaction Work-up

Chemical Risk Assessment: None
Biological Risk Assessment: Low
Protective Equipment: Lab coat, gloves

Supplies: None
Reagents: None
Equipment: None
Specimen Requirements: Post Transfusion Urine sample
Post Transfusion properly labeled EDTA tube: 6.0 mL pink top is preferred
3.0 mL or 10.0 mL lavender top is also acceptable
A properly labeled clot tube, no serum separator, may be used if EDTA is not available.
Refer to Specimen Labeling Requirements and BBID Numbers- BB.FD.1001

STEPS	INSTRUCTIONS	CHANGE/ APPROVAL
1.0	**The transfusionist will:** **1.1 Take actions as outlined in Blood Administration Policy and Procedure.** *Refer to WFBMC-169 Administration of Blood and Blood Components.*	
2.0	**Page the pathology resident for all reactions.** *Refer to E: Protocols: Step 12.0 for instructions on simple localized urticarial reactions.* **NOTE:** Phone calls received about possible transfusion reactions PRIOR to any reaction specimen should be considered potential transfusion reactions and reported to the pathology resident. 2.1 Relay pertinent information by paging Web on call or paging pathology resident. Web on call is an efficient way to relay the pertinent information while testing is in progress. 2.2 Provide the following information: • Patient's Name • MR # • Location and extension • Product • Testing in progress 2.3 Call the blood bank medical director if no response. 2.4 Document the date/time and who was called on the Suspected Adverse Transfusion Reaction Investigation Part II form Communication Section only.	
3.0	**The technologist will order the reaction in WakeOne when the specimens and paperwork arrive in the blood bank and receive in SCC.** *Refer to FD. Specimen Receipt, Section IV.* 3.1 Check that unit tag (Part I) is returned and completed. a. Return Part I to floor for completion if incomplete. b. Make a copy of incomplete Part I to retain until original returned.	

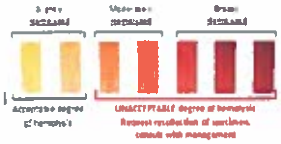
STEPS	INSTRUCTIONS	CHANGE/ APPROVAL
	c. Begin work-up while waiting for Part I to be returned. d. Obtain the Suspected Adverse Transfusion Reaction Investigation Part II form and complete the communication section. 3.2 Enter the special message TRX1 in SCC to indicate transfusion reaction in process and units have not been approved for issue without emergency release.	
4.0	**Go to Inventory>Edit>Status to check for additional parts, splits, or products with the same whole blood number.** 4.1 Enter only the whole blood number (not the product code) to pull up all products associated with the whole blood number. F12 to accept. 4.2 Change the status of any splits or products that are in inventory or allocated to Quarantine immediately. a. If they were issued, notify the pathology resident or medical director. b. Do NOT issue any part, split or other product without the approval of the medical director. 4.3 Document these tasks on Suspected Adverse Transfusion Reaction Investigation Part II – Communication Section.	
5.0	**Confirm the transfusion in SCC.** 5.1 Go to Patient>Transfusions>Confirm. a. NOTE: If unit is in a presumed/confirmed transfused status, then the following must be performed under Patient>Transfusion>Edit. b. If the reaction is due to a unit transfused at another facility, you cannot confirm the transfusion in SCC. *Refer to Attachment 3: Transfusion Reaction Work Flow* 5.2 Enter Patient's MRN number. 5.3 Choose the unit from the list and F12 to Accept. 5.4 Edit the date and time the transfusion started, if needed. 5.5 Enter the date and time transfusion ended. 5.6 Enter the transfusion Nurse's name. 5.7 Edit the volume transfused if desired. 5.8 Enter the observations (signs and symptoms of reaction) from the transfusion product tag. Up to five (5) observations can be entered. a. If more than 5 observations, then click F7 and add the additional observations in comment section. 5.9 F12 to accept and save the changes.	

STEPS	INSTRUCTIONS	CHANGE/ APPROVAL
	5.10 Select canned message 'Transfusion workup initiated' when TREAC (Transfusion Reaction) exception appears. F12 to accept.	
6.0	**Report any abnormalities in appearance in the blood bag.** Example: Hemolysis in the bag may indicate a solution other than saline was added. Discoloration, purple or brown, may suggest bacterial contamination. 6.1 Notify the pathology resident immediately if abnormality is present. *Refer to Protocols: Visual Inspection of Blood and Blood Products*	
7.0	**Request gram stain and culture on all components stored at room temperature or manipulated within the blood bank such as pooling, splitting washing, deglycerolized, etc. and/or as ordered by a physician.** 7.1 Complete a Clinical Laboratory Requisition form. 7.2 Notify the pathology resident immediately if the gram stain is positive. a. Pathology resident must notify the medical director and the patient's physician. b. The blood supplier will be notified by the medical director.	
8.0	**Result Transfusion Reaction Workup for Phase 1 (TRX1).** *Refer to Attachment 3: Transfusion Reaction Work Flow* 8.1 Go to Patient>Transfusion>Workup 8.2 Enter MRN if it does not default and F12 to accept. 8.3 Click OK if the message "Patient caution window has changed" is displayed. 8.4 Click Esc-Quit if the patient caution window opens to close it after review. 8.5 Double click the unit with the transfusion reaction; F12 to accept and Yes to save. 8.6 The system displays the Transfusion Reaction Result Screen with tests built for the Pre-Transfusion specimen, the Post-Transfusion specimen and the Unit testing. 8.7 Click F7-Results at each result field to open the resulting window. 8.8 Click the drop down to select the rack (QC) if not defaulted.	

STEPS	INSTRUCTIONS	CHANGE/ APPROVAL

8.9 *Refer to Table below for list of tests that can be resulted.*

a. Cancel any test that is not actually performed.

Test	Instructions
Hemolysis Check	1. Check for hemolysis: Pre and Post transfusion specimens. Select grade from drop down box. a. Grade as: NONE (0) , SLIGHT (SL), MODERATE (MD), MARKED (MK).  2. If hemolysis is present, verify with another sample (either from Core lab or new collection) that hemolysis is not mechanical hemolysis due to phlebotomy. 3. Notify the pathology resident immediately if hemolysis is present in both samples.
Icteric Check	1. Visually check for icterus in both the pre and post transfusion sample. 2. Grade as: +, -, NA in first column. 3. Interpret as POS or NEG in second column. Examples of icteric samples. 
Clerical Check	1. Perform a Clerical Check ON Pretransfusion Sample, Post transfusion sample and Unit involved following grid below.

	Patient Name		MRN #		BBID#		ABO/RH		Unit bag
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	
Specimen	X	X	X	X	X	X	X	X	
Issue slip	X		X						X
Computer	X		X				X	X	X
Requisitions	X		X		X	X	X	X	X
Other documents	X		X						X
Unit tag	X		X		X			X	X
Unit bag								X	X

<table>
<tr><th>STEPS</th><th>INSTRUCTIONS</th><th>CHANGE/ APPROVAL</th></tr>
<tr><td></td><td>
<table>
<tr><th>Test</th><th>Instructions</th></tr>
<tr><td>Clerical Check cont'd</td><td>2. Report any discrepancies immediately to: pathology resident or medical director and section manager.
3. Check records and specimens for other patients performed around the same timeframe to be sure there are no other patients at risk.
a. Each step of the process must be checked to find out if and where an error has occurred.</td></tr>
<tr><td>DAT – Gel, Poly, IgG, C3d, Control</td><td>1. Perform Direct Antiglobulin Test on the pre, if available, and post specimen. Check for mixed field on post specimen.
2. Grade the reactions for Poly, anti-IgG, Anti-C3d and IgG Gel DAT and enter in SCC.
a. Perform follow-up testing for a positive DAT on the post specimen.
3. Determine if Antibody Screen needs to be repeated based on Post Reaction DAT Results.

<table>
<tr><th>DAT Results</th><th>Instructions</th></tr>
<tr><td>Positive</td><td>Repeat the antibody screen on the pre and post transfusion samples</td></tr>
<tr><td>Negative</td><td>No need to repeat the antibody screen unless delayed or acute hemolytic reaction is suspected.</td></tr>
</table>

Refer to Specials: Direct Antiglobulin Test</td></tr>
<tr><td>Urine</td><td>1. Check post transfusion urine with dipstick for blood.
2. Select from drop down box the results.
<table>
<tr><th>Code</th><th>UHGB</th><th>Translation</th></tr>
<tr><td>NA</td><td>NOTDN</td><td>Not Done – Do NOT Use. Cancel test.</td></tr>
<tr><td>0</td><td>NEG</td><td>Neg</td></tr>
<tr><td>TR</td><td>TRACE</td><td>Trace</td></tr>
<tr><td>MD</td><td>MOD</td><td>Moderate</td></tr>
<tr><td>HT</td><td>H-TR</td><td>Hemolyzed Trace</td></tr>
<tr><td>HS</td><td>H-SM</td><td>Hemolyzed Small</td></tr>
<tr><td>HM</td><td>H-MOD</td><td>Hemolyzed Moderate</td></tr>
<tr><td>HL</td><td>H-LRG</td><td>Hemolyzed Large</td></tr>
</table>
3. Refer to Routine: Hemastix Procedure.</td></tr>
</table>
</td><td></td></tr>
</table>

<table>
<tr><th>STEPS</th><th>INSTRUCTIONS</th><th>CHANGE/ APPROVAL</th></tr>
<tr><td></td><td>
<table>
<tr><th>Test</th><th>Instructions</th></tr>
<tr><td>Urine Sediment</td><td>1. Centrifuge urine.
2. Observe the color of the sediment after centrifugation.
3. Select from drop down box.
<table>
<tr><th>Code</th><th>U-Sed</th><th>Translation</th></tr>
<tr><td>NA</td><td>NOTDN</td><td>Not applicable
– do NOT use
– cancel test.</td></tr>
<tr><td>NO</td><td>None</td><td>None</td></tr>
<tr><td>WH</td><td>White</td><td>White</td></tr>
<tr><td>BR</td><td>Brown</td><td>Brown</td></tr>
<tr><td>TN</td><td>Tan</td><td>Tan</td></tr>
<tr><td>PK</td><td>Pink</td><td>Pink</td></tr>
<tr><td>RD</td><td>Red</td><td>Red</td></tr>
</table></td></tr>
<tr><td>ABORh</td><td>1. Perform ABO/Rh on post-transfusion specimen.
2. Notify the medical director and manager immediately if results are discrepant.
Refer to: Attachment 1: Suspected Acute Hemolytic Reaction Due to Red Cell Incompatibility

Refer to: ABORh Testing Manual method; BB.Routine.1004</td></tr>
<tr><td>TXRN Review</td><td>1. Medical Director or Path Resident's interpretation of reaction.
2. Management or designee will enter into SCC.
Refer to Attachment 4,5</td></tr>
</table>
8.10 Enter a short comment or Click F4 to add a long comment.
8.11 F12 to save results and Yes to save.
</td><td></td></tr>
<tr><td>9.0</td><td>Print Report.
9.1 Go to Patient>Transfusion>Workup.
9.2 Enter MRN if it does not default in.
a. F12 to accept, then Esc-Quit and Enter to enter workup.
9.3 Click Ctrl+P-Report from the navigation bar to print and select printer.
9.4 Esc Quit to exit.
9.5 Document time called to Pathology Resident on printed copy.</td><td></td></tr>
</table>

STEPS	INSTRUCTIONS	CHANGE/ APPROVAL
10.0	**Inform the pathology resident of the results and perform any additional testing ordered.** 10.1 Record the event in the Adverse Reaction Investigation Log. a. Management or designee will document culture results and enter Medical Director comments into computer when transfusion reaction is finalized. 10.2 Remove special message TRX1 after pathologist approves additional products.	
11.0	**Refer to the following attachments for additional information for specific reaction types:** *Attachment 1: Suspected Hemolytic Reaction due to Red Cell Incompatibility*	

3. Review/Revised/implemented:

All procedures must be reviewed according to Document Control Protocol.
All new procedures and procedures that have major revisions must be signed by the CLIA Director.
All reviewed procedures and procedures with minor revisions can be signed by the designated section medical Director or designee.

4. Related Procedures:

Routine: Direct Antiglobulin Test
Routine: ABO/Rh Testing
Routine: Antibody Screen and Identification
Quality Plan: Deviations, Nonconformances, and Adverse Events
Special Procedures: General Guidelines for Look back
Special Procedures: Suspected Post Transfusion Infection
WFBMC-169 Administration of Blood and Blood Components

5. References:

Technical Manual, American Association of Blood Banks (AABB). Revised periodically
Standards for Blood Banks and Transfusion Services. Revised periodically.
7.2, 7.3, 7.5, 7.5.1, 7.5.1.1, 7.5.1.2, 7.5.2, 7.5.2.1, 7.5.2.2, 7.5.2.3, 7.5.2.4, 7.5.3
CAP Transfusion Medicine Checklist. Revised periodically.
TRM.41650, TRM.41750, TRM.41770, TRM.41800, TRM.41850, TRM.42000, TRM.42050, TRM.42060, TRM.42100, TRM.42110, TRM.42120, TRM.42135, TRM.42170, TRM.42185

6. Attachments:

Attachment 1: Suspected Hemolytic Reaction due to Red Cell Incompatibility
Attachment 2: Transfusion Reactions During Downtime
Attachment 3: Transfusion Reaction Work Flow
Attachment 4: Resulting the Pathologist's Transfusion Reaction Interpretation
Attachment 5: Finalizing a Transfusion Reaction Interpretation
Attachment 6: Adverse Reactions- CAP and AABB Standards

7. Revised/Reviewed Dates and Signatures:

See Document Change Control

Document Change Control			
Title: Investigation of Suspected Adverse Reactions to Transfusion			
Previous title:			
Written date		**Written by:**	
Validation date		**Validation by**	
Reviewed date		**Reviewed by**	
Approved date		**Approved by**	
Approved date		**Approved by**	
Effective date in use	**<10/3/2007**	**In use by**	**See archive history**

Revisions

Revised Date	By	MD Date	By	MD Date	By	Review Date	By	Effective Date	By
8/8/13	JHS	1/31/14	GP	1/31/14	EF	1/29/14	MRJ	2/3/14	JHS
Validate Date	**By**	**Revisions: Re-formatted. Clarified process if no sample received for simple localized urticarial reactions (allergic).**							
1/29/16	NJ								
Revised Date	**By**	**MD Date**	**By**	**MD Date**	**By**	**Review Date**	**By**	**Effective Date**	**By**
7/26/16	JHS	9/10/16	GP	8/2/16	EF	8/2/16	JHS	8/10/16	JHS
Validate Date	**By**	Revisions:21.0 added to E: A negative Direct Antiglobulin Test (DAT) does not rule out acute hemolysis if all transfused cells have been destroyed. The pathology resident will review the clinical picture and may request additional tests including the antibody screen on the post transfusion sample in these cases. Revised to reflect SCC computer system and entry directly into SCC.							
7/29/16	AM								
Revised Date	**By**	**MD Date**	**By**	**MD Date**	**By**	**Review Date**	**By**	**Effective Date**	**By**
10/2/17	JHS			12/1/17	EF	11/31/17	MRJ	12/4/17	JS
Validate Date	**By**	Revisions: Added 4.0 to page path resident as soon as a transfusion reaction is reported to the Blood Bank so that they can check on the clinical status of the patient. 5.0Notification of the pathology resident or medical director should occur before testing is started and the notification should be documented on the Suspected Adverse Transfusion Reaction Investigation Part II form including the name of the person notified. The Path Resident will decide if a work-up needs to be completed for reported allergic reactions.							
10/27/17	JJ								
Revised Date	**By**	**MD Date**	**By**	**MD Date**	**By**	**Review Date**	**By**	**Effective Date**	**By**
1/21/20	JJ			2/10/20		1-22-2020		2/18/2020	
Validate Date	**By**	Revisions: Changed electronic file location of procedure. Added special message of TRX1 in SCC. Added Att 6-AABB and CAP requirements. Added protocols 13 and 14: Special message TRX1 in SCC, Not to issue splits and parts. Added list of AABB standards and CAP requirements added to references. Added to Att 4-Dr Patel's SCC ID. Removed protocol 32. The Transfusion Safety Officer reports WFBMC adverse transfusion reactions to CDC (Hemovigilance Module). Att 4- updated pathologist SCC ID#s for Payne and Foster. Att 5- Removed Off page reference to Proceed to Charge for path services. Added note that resulting TXREV will charge for path services. Incorporated Att. 4 and 5 to this procedure and including document change controls.							
2.6.20	VA								

Locations		Out of Use: Date:		By	
		Reason			

Reviews: Record date/initials

Date	Initials	Date	Initials	Date	Initials	Date	Initials
11/5/15	MRJ						
9/7/17	JHS						

Attachment 1: Suspected Hemolytic Reaction due to Red Cell Incompatibility

<table>
<tr><th>STEPS</th><th>INSTRUCTIONS</th><th>CHANGE/ APPROVAL</th></tr>
<tr><td>1.0</td><td>Add the Phase 2 work up to the Transfusion Work up order in SCC.

1.1 Go to Patient >Transfusion>Workup
1.2 Enter Patient's MRN.
1.3 Select unit with reaction and enter.
1.4 Click Ctrl+T to add Phase 2 testing for a hemolytic reaction to the current transfusion reaction order.</td><td></td></tr>
<tr><td>2.0</td><td>Perform the following serological testing indicated in the table below.

2.1 Click F7-Results at each result field to open the resulting window.
2.2 Enter results into SCC.

<table>
<tr><th>Test</th><th>Instructions</th></tr>
<tr><td>ABO

Rh</td><td>1. Perform ABO/Rh on pre and post transfusion specimen.
2. Enter results into SCC.
3. Select interpretation.
4. Notify the medical director and manager immediately if results are discrepant.</td></tr>
<tr><td>ABS</td><td>1. Perform the antibody screen on the pre and post transfusion specimen in the media that it was originally performed.
2. Enter results into SCC.
3. Select interpretation

Refer to Routine: Antibody Screen Procedure</td></tr>
<tr><td>XMP</td><td>1. Perform the full crossmatch which includes the immediate spin and antiglobulin phase on the pre and post transfusion specimen.
2. Perform using the antiglobulin media of the original crossmatch or PEG if antiglobulin not performed originally.
3. Enter results into SCC.
4. Select interpretation.

Refer to Routine: Crossmatch Procedure</td></tr>
</table>

2.3 Report to the pathology resident, medical director and manager.</td><td></td></tr>
</table>

<table>
<tr><th>STEPS</th><th>INSTRUCTIONS</th><th>CHANGE/ APPROVAL</th></tr>
<tr><td>3.0</td><td>Send specimens for additional testing as ordered by the pathology resident and/or medical director.

3.1 Additional testing may include; but, not limited to: H/H, Total Bili., 5-7 hrs. post reaction, haptoglobin, coagulation studies, urinalysis, other as directed.</td><td></td></tr>
<tr><td>4.0</td><td>The medical director is responsible for review and notifying/follow-up with the patient's physician.</td><td></td></tr>
<tr><td>5.0</td><td>Delayed hemolytic reactions are ordered and tested as in steps 1-4 above.

5.1 Pull previous specimen (last negative screen but not current sample), if available, and repeat antibody screen with method used on that sample.
5.2 Notify management if antibody is detected in previously negative specimen. Management will direct testing in different medias.
5.3 Obtain segments from units previously transfused and antigen type.
5.4 Review Direct Antiglobulin Results and take actions as outlined below.

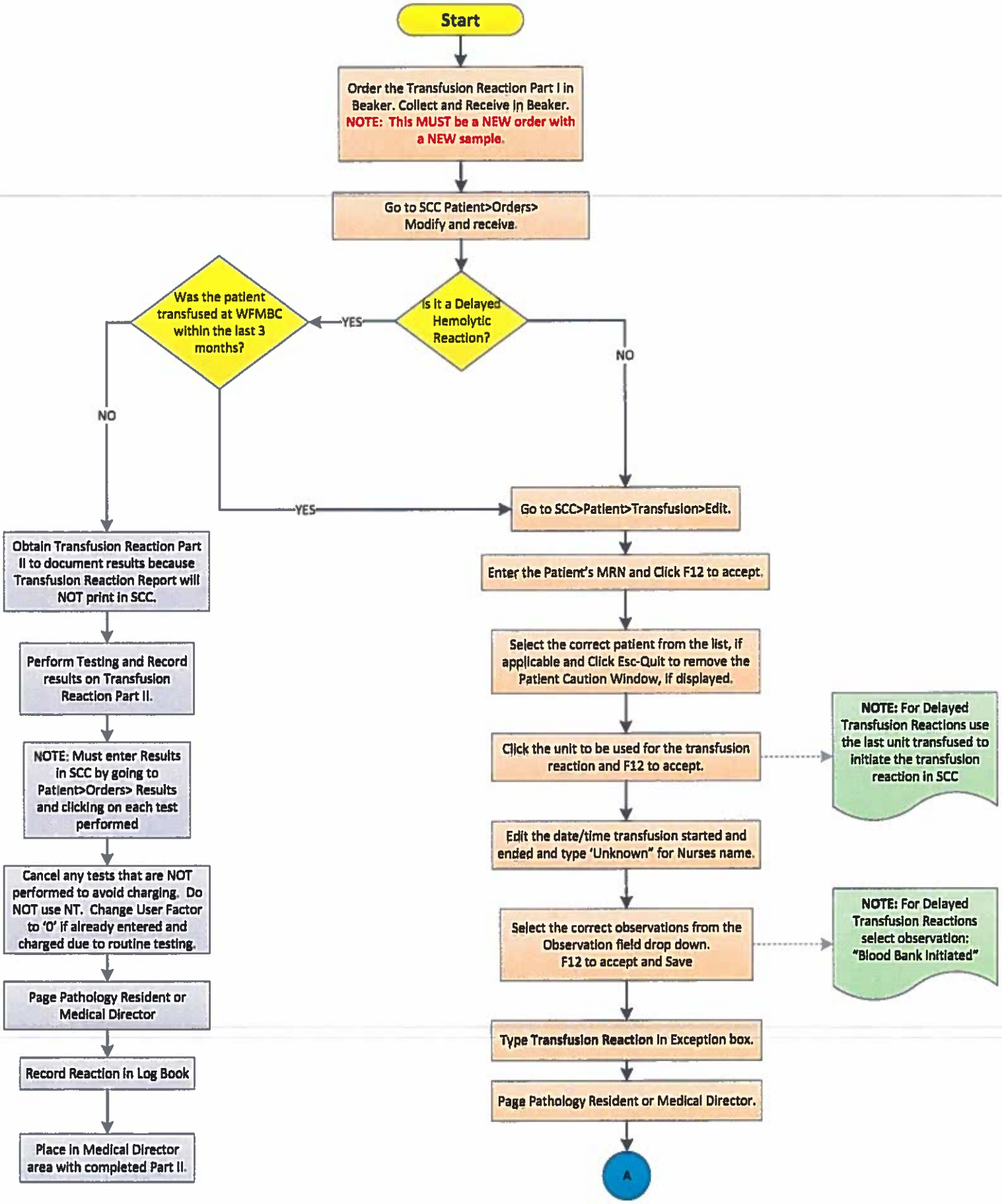
<table>
<tr><th>DAT Results</th><th>Actions</th></tr>
<tr><td>Negative</td><td>a. Follow procedures for obtaining compatible units.
b. It is NOT necessary to initiate a transfusion reaction investigation unless the new antibody identified is anti-Jka or anti-Jkb. For Kidd antibodies – test DAT (Poly, IgG, C3d, Gel) and consult with management.</td></tr>
<tr><td>Positive</td><td>a. Initiate a transfusion reaction investigation form and record results.
b. Notify the pathology resident
c. Follow procedures for obtaining compatible units.
d. Do NOT issue any blood/blood products until the pathology resident has reviewed the reaction and given approval.
e. Perform any additional testing according to instructions
f. Crossmatch subsequent units using the plasma and eluate (if eluate is positive and unable to identify antibody in eluate)</td></tr>
</table>
</td><td></td></tr>
</table>

Attachment 2: Transfusion Reactions During Downtime

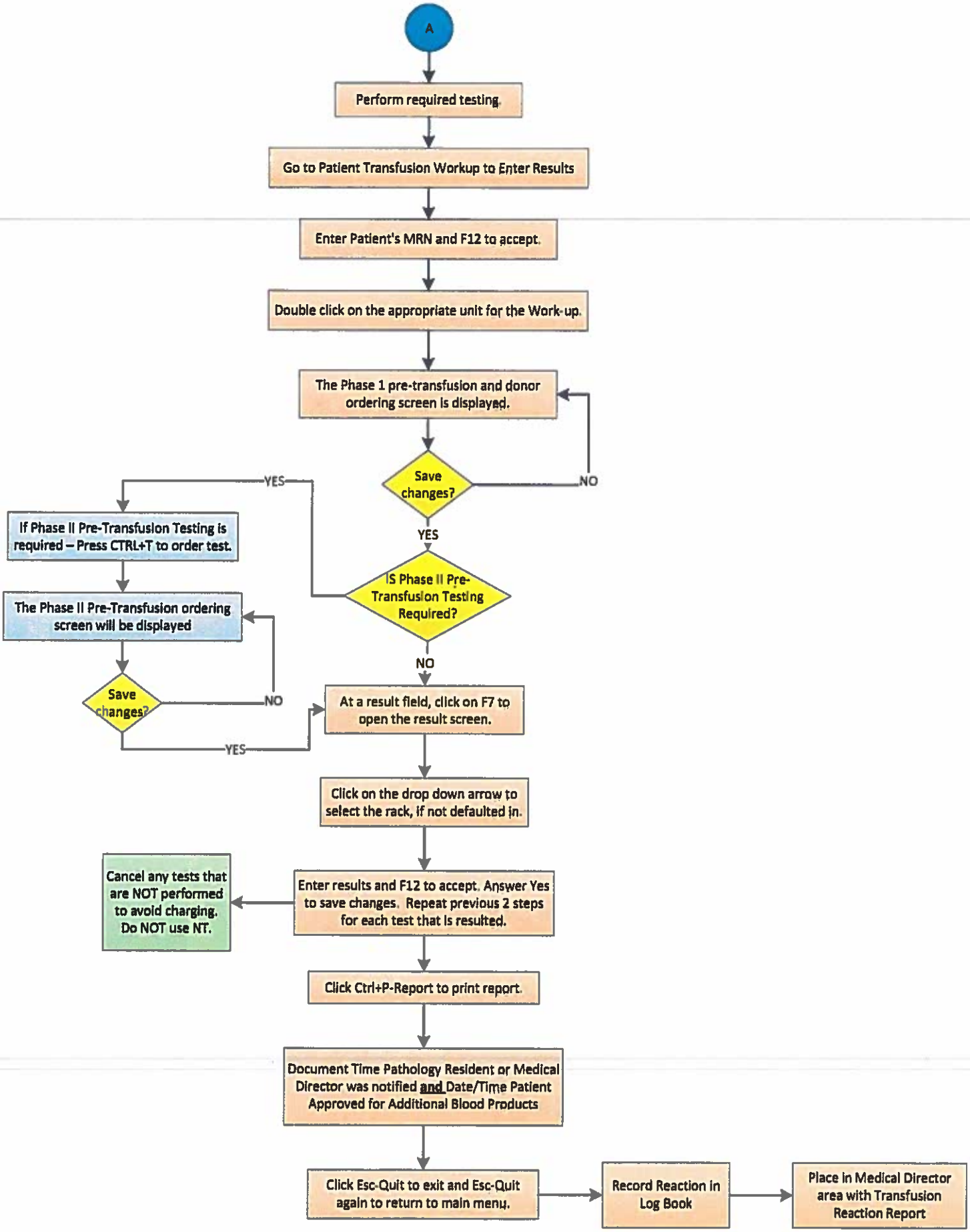
STEPS	INSTRUCTIONS	CHANGE/ APPROVAL
1.0	**Obtain Suspected Adverse Transfusion Reaction Investigation – Part II.** **1.1** Complete clerical check and testing as outlined in the transfusion reaction procedure.	
	1.2 Document results on Suspected Transfusion Reaction Investigation – Part II form. **1.3** Document suspected hemolytic reactions on Investigation of Hemolytic Transfusion Reaction form – Part III. **1.4** Enter results into SCC when computer system becomes available. **1.5** Initial and date the downtime form and record entered into SCC. **1.6** Record transfusion reaction in the Transfusion Reaction Log book. **1.7** Leave for Blood Bank Medical Director review on next business day.	

TRANSFUSION REACTION FLOWCHART

ATTACHMENT 3

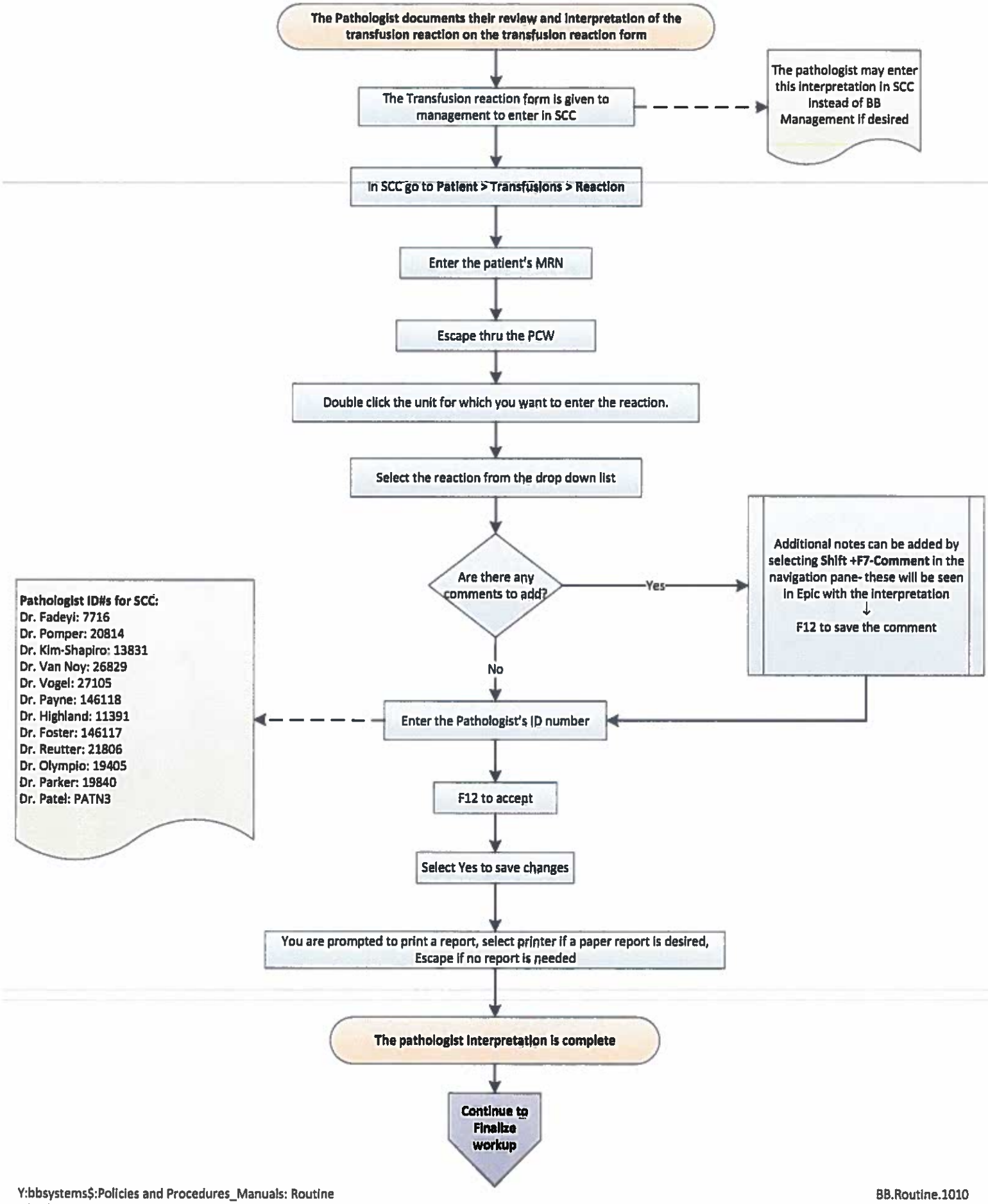


TRANSFUSION REACTION FLOWCHART



RESULTING THE PATHOLOGIST'S TRANSFUSION REACTION INTERPRETATION

ATTACHMENT 4



FINALIZING A TRANSFUSION REACTION INTERPRETATION

Finalize workup

Go to Patient > Transfusion > Workup
(or just click on Workup if you are still in Patient > Transfusion)

Enter MRN if needed

A message will appear that the PCW has changed, you can see the transfusion reaction showing in the PCW now. Press Escape to exit the PCW

Double click the unit for which you want to enter the reaction.

Go to the Post Transfusion row

Scroll to the right, over to the TXREV box and click on box to place cursor in box

Hit F7 to open the result field

You will be prompted to enter a Rack before you can proceed.

Select a Daily rack (if not already selected) in order to proceed

Resulting the TXREV will charge for the Pathology consult

Result the two TXREV field:
The first field result with a *
The second field result as Done
F12 to save

The transfusion reaction will display in Epic with the pathologist's interp, unit # and product Ecode plus any comments added to the interp

Screen shot of Epic results:

ATTACHMENT 6

ADVERSE REACTIONS- CAP AND AABB STANDARDS

CAP Requirements:

TRM.41650 Transfusion Reaction Recognition

There are written procedures describing the criteria for the recognition of transfusion reactions, and the clinical actions to be taken in the event of a suspected transfusion reaction.

TRM.41750 Reporting of Transfusion Reactions and Incidents

Policies require that suspected transfusion reactions or incidents are reported immediately to the laboratory.

TRM.41770 System Failure

When an incident investigation indicates a system failure (eg, misadministration of a blood product), the transfusion service medical director is involved in the investigation and resolution of the issue.

TRM.41800 Post Transfusion Specimen Storage

Donor and recipient blood samples are appropriately stored for at least 7 days after transfusion for retesting, in the event of a transfusion reaction.

TRM.41850 Investigation of Suspected Hemolytic Transfusion Reaction

The immediate investigation of a suspected hemolytic transfusion reaction includes all of the following.

1. **Examination of patient identification, blood unit labels, and all pre-reaction records for possible errors in patient or blood identification at the bedside and in the laboratory**
2. **Visual examination of post-reaction and pre-reaction (if available) serum or plasma for evidence of hemolysis**
3. **ABO and direct antiglobulin test on post-reaction patient (recipient) blood sample**

TRM.42000 Additional Transfusion Reaction Evaluation

The transfusion service medical director has established a written procedure indicating under what circumstances additional testing will be done after a suspected transfusion reaction (including delayed transfusion reactions), and the nature of that testing.

TRM.42050 Transfusion Reaction Interpretation

The findings of an adverse reaction investigation are interpreted by the transfusion service medical director or designee, and reported in a timely and effective manner.

TRM.42060 Transfusion Reaction Monitoring

The transfusion service tracks the incidence of transfusion reactions and monitors the rate of transfusion reactions by each reaction type (eg, febrile, hemolytic, TRALI, etc.).

TRM.42100 Blood Supplier/Testing Laboratory Notification

There is a written procedure to notify the blood supplier or laboratory responsible for the pretransfusion testing (if performed by another laboratory) when blood components are a suspected primary cause of an adverse reaction (eg, hemolytic transfusion reaction, transfusion-related acute lung injury, transfusion-transmitted infection).

TRM.42110 TRALI

The laboratory has written policies and procedures to recognize, investigate and reduce the risk of transfusion-related acute lung injury (TRALI).

TRM.42120 Blood Component Recall and Quarantine

There is a procedure to identify and quarantine suspect blood components in the inventory when notice is received about donors who have tested reactive for an infectious disease and/or have been recalled by the supplier.

TRM.42135 Blood Supplier Notifications

The transfusion service has a procedure for managing quarantines, recalls, and market withdrawals issued by its blood suppliers.

TRM.42170 Notification of Providers and Recipients

The transfusion service has a written procedure consistent with national, federal, state and local regulations and guidances for notification and counseling, as appropriate (eg, components potentially infectious for HCV and HIV), of providers and recipients of a potentially infectious blood component.

TRM.42185 CBER Notification

There is a policy requiring notification of the appropriate agency when a transfusion-related fatality occurs following transfusion of any component.

AABB Standards:

7.2 Fatality Reporting

Fatalities confirmed to be caused by blood donation or blood transfusion shall be reported to outside agencies as required.

7.3 Classifying Adverse Events

The BB/TS shall use nationally recognized classifications for donor and patient adverse events. The medical director shall participate in the development of protocols used by the staff to identify, evaluate and report adverse events.

7.3.1 Internationally recognized classifications shall be used when no national classifications exist.

7.5 Adverse Events Related to Transfusion

There shall be a process for the administration of blood and blood components that includes the recognition, evaluation, and reporting of suspected transfusion-related adverse events.

7.5.1 Recognition of and Response to Transfusion Reactions

There shall be processes and procedures for the transfusing staff for the recognition of and response to transfusion reactions and for the recording of relevant information in the patient's medical record.

7.5.1.1 The process shall include:

1) Definition of signs and symptoms of suspected transfusion reactions.
2) Indications for interruption or discontinuation of the transfusion.
3) Evaluation and the timely clinical management of the patient.

7.5.1.2 When the transfusion is discontinued, the following shall be performed immediately:

1) The label on the blood containers and records shall be examined to detect errors in identifying the patient, blood or blood component.
2) The recipient's physician shall be notified.
3) Except in the cases of signs and symptoms suggestive of mild allergic reactions (eg, urticarial)
   a) The BB/TS shall be notified.
   b) The blood container (whether or not it contains any blood) shall be sent to the BB/TS with, whenever possible, the attached transfusion set and intravenous solutions.
   c) A post transfusion sample shall be obtained from the patient and sent to the BB/TS.

7.5.2 Laboratory Evaluation and Reporting of transfusion Reactions

The BB/TS shall have policies, processes, and procedures for the evaluation and reporting of suspected transfusion reactions, including evaluation, review of clerical information by the BB/TS, and notification of the BB/TS medical director.

7.5.2.1 For suspected hemolytic transfusion reactions the evaluation shall include the following:

1) The patient's posttransfusion reaction serum or plasma shall be inspected for evidence of hemolysis. Pretransfusion samples shall be used for comparison.

2) A repeat ABO group determination shall be performed on the posttransfusion sample. If the result is positive, the most recent pretransfusion sample shall be used for comparison.

3) A direct antiglobulin test shall be performed on the posttransfusion sample. If theresult is positive, the most recent pretransfusion sample shall be used for comparison.

4) The BB/TS shall have a process for indicating under what circumstances additional testing shall be performed and what that testing shall be.

5) Review and interpretation by the medical director.

7.5.2.2 The BB/TS shall have a process for evaluations for suspected nonhemolytic transfusion reactions including, but not limited to, febrile reactions, possible bacterial contamination, and TRALI.

7.5.2.3 Interpretation of the evaluation shall be recorded in the patient's medical record and, if suggestive of hemolysis, bacterial contamination, TRALI, or other serious adverse event related to transfusion, the interpretation shall be reported to the patient physician immediately.

7.5.2.4 When a transfusion fatality or other serious, unexpected adverse event occurs that is suspected to be related to an attribute of a donor or a unit, the collecting facility shall be notified immediately and subsequently in writing.

7.5.3 Delayed Transfusion Reactions (Antigen-Antibody Reactions)

If a delayed transfusion reaction is suspected or detected, tests shall be performed to determine the cause. The results of the evaluation shall be reported to the patient's physician and recorded in the patient's medical record.