

New York Blood Center Enterprises Suspected Transfusion Related Adverse Event

Instructions: For all adverse events, complete sections 1, 2 and 3.

In addition, for:

- suspected transfusion transmitted infectious disease events (other than bacterial), complete section 4.
- suspected TRALI reactions, complete section 5.
- suspected bacterial contamination events, complete section 6.

You may be required to report this adverse event to your state department of health. Follow your local procedures for state reporting.

Please sign the last page and submit the completed form to the **facility that shipped implicated blood unit(s) to you**. Contact information for each facility is included below.

<p><u>Community Blood Centers- Kansas City</u></p> <ul style="list-style-type: none">• TRALI- Fax to IRL at 816-277-0757 or email to Immuno@cbckc.org <p>Contact IRL immediately if TRALI is involved in a patient fatality (816-968-4053)</p> <ul style="list-style-type: none">• Bacterial Contamination – Fax to QM at 816-277-0798 or email to QAGroupALL@cbckc.org• Post Transfusion Disease- Fax to Donor Notification at 816-277-0785 or email to TherapeuticCollectionServices@cbckc.org	<p><u>New York Blood Center</u></p> <p>Special Donor Services Department</p> <ul style="list-style-type: none">• Phone: 800-688-0900• Fax: 212-288-8464
<p><u>Blood Bank of Delmarva</u></p> <p>Submit reports through Blood Hub. If not available, send report to:</p> <p>Reference Laboratory</p> <ul style="list-style-type: none">• Fax: 302-709-6155• Then call 302-737-8405 ext. 716	<p><u>Rhode Island Blood Center</u></p> <p>Laboratory Supervisor</p> <ul style="list-style-type: none">• Phone: 401-453-8374• Fax: 401-248-5750
<p><u>Innovative Blood Resources</u> Memorial Blood Centers Nebraska Community Blood Bank</p> <p>Physician Services Donor Advocates</p> <ul style="list-style-type: none">• Phone 651-332-7287, Fax 651-332-7001	

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1	FACILITY INFORMATION AND DESCRIPTION OF EVENT	
Reporting Facility Information		
Date of Report:	Name of person reporting:	Title of person reporting:
Telephone number:	Email address:	
Reporting Facility Name:	Reporting Facility Address:	
Transfusion Medicine Physician Name:	Transfusion Medicine Physician Phone Number:	
Select Suspected Category for Adverse Event:		
Check all that apply ▶	<input type="checkbox"/>	Anaplasma
	<input type="checkbox"/>	Babesiosis
	<input type="checkbox"/>	HBV
	<input type="checkbox"/>	HCV
	<input type="checkbox"/>	HIV 1-2
	<input type="checkbox"/>	HTLV I-II
	<input type="checkbox"/>	Septic Transfusion Reaction (Bacterial Contamination)
	<input type="checkbox"/>	Transfusion Related Acute Lung Injury (TRALI)
	<input type="checkbox"/>	Other ▼ (if selected, describe below)
Additional Information ▶		

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2	PATIENT INFORMATION	
Patient Recipient General Information		
Medical Record Number:	Patient Date of Birth:	Patient Sex: <input type="checkbox"/> Female <input type="checkbox"/> Male
Medical Information		
Attending Physician Name:		Attending Physician Phone Number:
Admitting or Primary Diagnosis:		Indication for Transfusion:
Relevant Severe Co-Morbidities (if applicable):	Current Status of Patient:	
	<input type="checkbox"/> Expired (Transfusion Related fatality) ** Report to FDA within 24 hours	
	<input type="checkbox"/> Reaction continues	
	<input type="checkbox"/> Returned to pre-transfusion status	
	<input type="checkbox"/> Unknown	
<input type="checkbox"/> Other ▼ describe if other:		
Treatment and Clinical Course		
Treatment	Check all Treatments Administered	Indicate YES if patient Responded to administered treatment
Acetaminophen	<input type="checkbox"/> YES	<input type="checkbox"/> YES
Antihistamines	<input type="checkbox"/> YES	<input type="checkbox"/> YES
Bronchodilators	<input type="checkbox"/> YES	<input type="checkbox"/> YES
Diuretics	<input type="checkbox"/> YES	<input type="checkbox"/> YES
Epinephrine	<input type="checkbox"/> YES	<input type="checkbox"/> YES
Intubation Ventilatory Support	<input type="checkbox"/> YES	<input type="checkbox"/> YES
Oxygen Supplementation	<input type="checkbox"/> YES	<input type="checkbox"/> YES
Steroids	<input type="checkbox"/> YES	<input type="checkbox"/> YES
Other (specify) ►	<input type="checkbox"/> YES	<input type="checkbox"/> YES
Describe if Other :		
Additional Comments:		

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<i>(Patient Information continued from previous page)</i>		
Pre-Transfusion Vital Signs		
Date of Pre-Transfusion Vital Signs:	Time of Pre-Transfusion Vital Signs <i>hh:mm</i>	Temperature: indicate °C or °F
Blood Pressure (Systolic/Diastolic) mm Hg	Pulse(bpm)	Respiratory Rate(rpm)
Post Transfusion Vital Signs		
Date of Post-Transfusion Vital Signs:	Time of Post-Transfusion Vital Signs hh:mm	Temperature: indicate °C or °F
Blood Pressure (Systolic/Diastolic) mm Hg	Pulse(bpm)	Respiratory Rate(rpm)

3	BLOOD COMPONENTS	
Reaction Information		
Date of Reaction:	Time of Reaction (<i>hh:mm</i>)	
Clinical Description of Reaction:		
Does the patient have a history of transfusion reactions? <input type="checkbox"/> YES ▼ <input type="checkbox"/> NO		
Describe each reaction if YES was selected and specify dates:		
Suspected Unit Information		
1-DIN:	1-Component Type:	
1- Date of transfusion	1-Start Time of Unit Transfusion (<i>hh:mm</i>)	2-End Time of Unit Transfusion(<i>hh:mm</i>)
2-DIN:	2-Component Type:	

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2- Date of transfusion	2-Start Time of Unit Transfusion (hh:mm)	2-End Time of Unit Transfusion(hh:mm)
3-DIN:	3-Component Type:	
3- Date of transfusion	3-Start Time of Unit Transfusion (hh:mm)	3-End Time of Unit Transfusion(hh:mm)
4-DIN:	4-Component Type:	
4- Date of transfusion	4-Start Time of Unit Transfusion (hh:mm)	4-End Time of Unit Transfusion(hh:mm)
5-DIN:	5-Component Type:	
5- Date of transfusion	5-Start Time of Unit Transfusion (hh:mm)	5-End Time of Unit Transfusion(hh:mm)
6-DIN:	6-Component Type:	
6- Date of transfusion	6-Start Time of Unit Transfusion (hh:mm)	6-End Time of Unit Transfusion(hh:mm)
7-DIN:	7-Component Type:	
7 Date of transfusion	7-Start Time of Unit Transfusion (hh:mm)	7-End Time of Unit Transfusion(hh:mm)
8-DIN:	8-Component Type:	
8- Date of transfusion	8-Start Time of Unit Transfusion (hh:mm)	8-End Time of Unit Transfusion(hh:mm)
9-DIN:	9-Component Type:	
9- Date of transfusion	9-Start Time of Unit Transfusion (hh:mm)	9-End Time of Unit Transfusion(hh:mm)

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10-DIN:	10-Component Type:	
10- Date of transfusion	10-Start Time of Unit Transfusion (hh:mm)	10-End Time of Unit Transfusion(hh:mm)
Specify any modifications made to units:		

4	INFECTIOUS DISEASE AND TESTING
Infectious Diseases	
Has the patient been assessed for risks from exposure (e.g. IV drug use, tattoos, acupuncture-ear piercing-venereal disease-sexual contact with infected partner)? <input type="checkbox"/> YES explain below	
<input type="checkbox"/> NO	
Could the event be related to causes other than the transfusion (dialysis-receipt of clotting factors in the past-occupational exposure to blood or body fluids-needle stick-spill-bite)? <input type="checkbox"/> YES explain below	
<input type="checkbox"/> NO	
Explain (if YES):	
Testing	
Was the recipient tested for this infectious disease prior to transfusion? <input type="checkbox"/> YES	
<input type="checkbox"/> NO	
List application Pre and Post Txn test results below:	
Hepatitis Testing	
PRE-TXN	POST-TXN
Pre-Txn test Date:	Post-Txn test Date:
Pre-Txn HBsAg Result:	Post-Txn HBsAg Result:
Pre-Txn Anti-HBs Result:	Post-Txn Anti-HBs Result:
Pre-Txn Anti-HBc Result:	Post-Txn Anti-HBc Result:
Pre-Txn Anti-HCV Result:	Post-Txn Anti-HCV Result:

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Pre-Txn HBV PCR Result:	Post-Txn HBV PCR Result:
Pre-Txn HCV PCR Result:	Post-Txn HCV PCR Result:
HIV Testing	
PRE-TXN	POST-TXN
HIV Pre-Txn Test Date	HIV Post-Txn Test Date
Pre-Txn Anti-HIV Result	Post-Txn Anti-HIV Result
Pre-Txn HIV PCR Result	Post-Txn HIV PCR Result
Other HIV Tests (Specify and provide result):	
Babesiosis Testing	
PRE-TXN	POST-TXN
Babesiosis Pre-Txn Testing Date:	Babesiosis Post-Txn Testing Date:
Pre-Txn Antibody Result:	Post-Txn Antibody Result:
Pre-Txn PCR Result:	Post-Txn PCR Result:
Additional Testing	
Other Testing:	Other Test Pre-Txn Date: Other Test Post-Txn Date:
Other Test Pre-Txn Result:	Other Test Post-Txn Result:

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5	TRALI REACTION INFORMATION		
Risk Factors for Acute Lung Injury check all that apply ▼			
<input type="checkbox"/> Acute Pancreatitis <input type="checkbox"/> Acute Respiratory Distress Syndrome(ARDS) <input type="checkbox"/> Amiodarone <input type="checkbox"/> Aspiration <input type="checkbox"/> Burn <input type="checkbox"/> Cardiopulmonary Bypass <input type="checkbox"/> Chemotherapy	<input type="checkbox"/> Diffuse Alveolar Damage <input type="checkbox"/> Disseminated Intravascular Coagulation <input type="checkbox"/> Drug Overdose <input type="checkbox"/> Lung Contusion <input type="checkbox"/> Massive Blood Transfusion <input type="checkbox"/> Multiple Trauma <input type="checkbox"/> Near Drowning	<input type="checkbox"/> Pneumonia <input type="checkbox"/> Severe Sepsis <input type="checkbox"/> Shock <input type="checkbox"/> Renal Failure <input type="checkbox"/> Radiation to Thorax <input type="checkbox"/> Upper Airway Obstruction <input type="checkbox"/> Toxic Inhalation	
Additional Comments (Other risk factors):			
Pre-Transfusion Diagnostics			
	Diagnostic Test	Test performed?	Pre-Transfusion Values
1	O2 sat ≤ 90% on room air	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> Not Performed	Pre-Txn Value:
2	PaO2FIO2 ≤ 300mm Hg	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> Not Performed	Pre-Txn Value:
3	Chest X-ray: Bilateral infiltrates	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> Not Performed	
4	Chest X-Ray: Widened Cardiac Silhouette (Cardiomegaly)	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> Not Performed	
5	Elevated BNP (Provide value in pg per mL)	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> Not Performed	Pre-Txn Value:
6	Elevated Central Venous Pressure greater than 12mm Hg (Provide values.)	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> Not Performed	Pre-Txn Value:
7	Elevated Pulmonary Artery Pressure greater than 18 mm Hg (Provide values.)	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> Not Performed	Pre-Txn Value:

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8	Positive Fluid Value (in mL)	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> Not Performed	Pre-Txn Value:
9	Transient decrease White Blood Cell Count	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> Not Performed	Pre-Txn Value:
Post-Transfusion Diagnostics			
Diagnostic Test		Test performed?	Post-Transfusion Values
1	O2 sat ≤ 90% on room air	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> Not Performed	Post-Txn Value:
2	PaO2/FIO2 ≤ 300mm Hg	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> Not Performed	Post-Txn Value:
3	Chest X-ray: Bilateral infiltrates	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> Not Performed	
4	Chest X-Ray: Widened Cardiac Silhouette (Cardiomegaly)	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> Not Performed	
5	Elevated BNP (Provide value in pg per mL)	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> Not Performed	Post-Txn Value:
6	Elevated Central Venous Pressure greater than 12mm Hg (Provide values.)	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> Not Performed	Post-Txn Value:
7	Elevated Pulmonary Artery Pressure greater than 18 mm Hg (Provide values.)	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> Not Performed	Post-Txn Value:
8	Positive Fluid Value (in mL)	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> Not Performed	Post-Txn Value:
9	Transient decrease White Blood Cell Count	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> Not Performed	Post-Txn Value:
If TRALI is diagnosed, please provide the following:			
Recipient HLA Type:		Recipient HNA Type:	Recipient HLA-HNA antibody status and identification:

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Donor HLA-HNA antibody status and identification (if performed on unit):	Donor HLA type (if available)
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6	BACTERIAL CONTAMINATION
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Suspected Bacterial Contamination Questions

Were the suspected units returned to the blood bank? <input type="checkbox"/> YES <input type="checkbox"/> NO	On reinspection does the component present any abnormalities (e.g. clumps, discoloration, hemolysis)? <input type="checkbox"/> YES <input type="checkbox"/> NO	Describe abnormalities (if any):
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Suspect Component- Source Used: <input type="checkbox"/> Bag <input type="checkbox"/> Segment <input type="checkbox"/> Not performed	Does the patient have history of fever or of other infection-related to his / her underlying medical condition? <input type="checkbox"/> YES <input type="checkbox"/> NO
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Was the patient on antibiotics at the time of transfusion? <input type="checkbox"/> YES ► <input type="checkbox"/> NO	Specify antibiotic (if YES):
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Is the patient currently being treated with antibiotics? <input type="checkbox"/> YES ► <input type="checkbox"/> NO	Specify antibiotic (if YES):
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Did the patient have an absolute neutropenia count (neutrophil less than 500 per µl) prior to transfusion? <input type="checkbox"/> YES <input type="checkbox"/> NO

Additional Comments:

Suspected Bacterial Contamination Additional Testing

Gram Stain Results for unit: <input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Not Done	Result (Organism):
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Culture Performed on unit: <input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Pending <input type="checkbox"/> Not Done	Result (Organism):
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Was a secondary test performed by the hospital for this component (PGD or equivalent)? <input type="checkbox"/> YES ► <input type="checkbox"/> NO		Specify test performed if YES :	
Patient Pre-Transfusion Blood Culture <input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Pending <input type="checkbox"/> Not Done	Date of Pre-Transfusion Culture:	Result of Pre-Transfusion Culture (Organism):	
Patients Post-Transfusion Blood Culture: <input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Pending <input type="checkbox"/> Not Done	Date of Post-Transfusion Culture	Result of Post-Transfusion Culture (Organism)	

Signature of person reporting	Signature:	Date:
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Submit the completed form to the facility that shipped implicated blood unit(s).