New York Blood Center Enterprises Suspected Transfusion Related Adverse Event

***Instructions**: For <u>all</u> 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 <u>facility that shipped implicated blood</u> unit(s) to you. Contact information for each facility is included below.

<u>Community Blood Centers- Kansas City</u>

- TRALI- Fax to IRL at 816-277-0757 or email to Immuno@cbckc.org

Contact IRL immediately if TRALI is involved in a patient fatality (816-968-4053)

- 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

<u>New York Blood Center</u>

Special Donor Services Department

- Phone: 800-688-0900
- Fax: 212-288-8464

<u>Blood Bank of Delmarva</u>

Submit reports through Blood Hub. If not available, send report to:

Reference Laboratory
- Fax: 302-709-6155
- Then call 302-737-8405 ext. 716

<u>Rhode Island Blood Center</u>

Laboratory Supervisor
- Phone: 401-453-8374
- Fax: 401-248-5750

<u>Innovative Blood Resources</u>
Memorial Blood Centers
Nebraska Community Blood Bank

Physician Services Donor Advocates

- Phone 651-332-7287, Fax 651-332-7001

New York Blood Center Enterprises Suspected Transfusion Related Adverse Event

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 ▶	☐	Anaplasma
	☐	Babesiosis
	☐	HBV
	☐	HCV
	☐	HIV 1-2
	☐	HTLV I-II
	☐	Septic Transfusion Reaction (Bacterial Contamination)
	☐	Transfusion Related Acute Lung Injury (TRALI)
	☐	Other ▼ (if selected, describe below)
Additional Information ▶		

New York Blood Center Enterprises Suspected Transfusion Related Adverse Event

2	PATIENT INFORMATION

Patient Recipient General Information

Medical Record Number:	Patient Date of Birth:	Patient Sex: ☐ Female ☐ 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:
	☐ Expired (Transfusion Related fatality) ** *Report to FDA within 24 hours*
	☐ Reaction continues
	☐ Returned to pre-transfusion status
	☐ Unknown
	☐ Other ▼ *describe if other:*

Treatment and Clinical Course

Treatment	Check all Treatments Administered	Indicate YES if patient Responded to administered treatment
Acetaminophen	☐ YES	☐ YES
Antihistamines	☐ YES	☐ YES
Bronchodilators	☐ YES	☐ YES
Diuretics	☐ YES	☐ YES
Epinephrine	☐ YES	☐ YES
Intubation Ventilatory Support	☐ YES	☐ YES
Oxygen Supplementation	☐ YES	☐ YES
Steroids	☐ YES	☐ YES
Other (specify) ▶	☐ YES	☐ YES

Describe if **Other**:

Additional Comments:

New York Blood Center Enterprises Suspected Transfusion Related Adverse Event

(Patient Information continued from previous page)		
Pre-Transfusion Vital Signs		
Date of Pre-Transfusion Vital Signs:	Time of Pre-Transfusion Vital Signs *hh:mm*	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 (*hh:mm)*	
Clinical Description of Reaction:		
Does the patient have a history of transfusion reactions?	☐ YES ▼ ☐ 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 *(hh:mm)*	2-End Time of Unit Transfusion(*hh:mm*)
2-DIN:	2-Component Type:	

New York Blood Center Enterprises Suspected Transfusion Related Adverse Event

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*)

New York Blood Center Enterprises Suspected Transfusion Related Adverse Event

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)?	☐ YES explain below ☐ 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)?	☐ YES explain below ☐ NO

Explain (if **YES**):

Testing

Was the recipient tested for this infectious disease prior to transfusion?	☐ YES ☐ 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:

New York Blood Center Enterprises Suspected Transfusion Related Adverse Event

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:	

New York Blood Center Enterprises Suspected Transfusion Related Adverse Event

5	TRALI REACTION INFORMATION

Risk Factors for Acute Lung Injury check all that apply ▼

☐ Acute Pancreatitis	☐ Diffuse Alveolar Damage	☐ Pneumonia
☐ Acute Respiratory Distress Syndrome(ARDS)	☐ Disseminated Intravascular Coagulation	☐ Severe Sepsis
☐ Amiodarone	☐ Drug Overdose	☐ Shock
☐ Aspiration	☐ Lung Contusion	☐ Renal Failure
☐ Burn	☐ Massive Blood Transfusion	☐ Radiation to Thorax
☐ Cardiopulmonary Bypass	☐ Multiple Trauma	☐ Upper Airway Obstruction
☐ Chemotherapy	☐ Near Drowning	☐ Toxic Inhalation

Additional Comments (Other risk factors):

Pre-Transfusion Diagnostics

	Diagnostic Test	Test performed?	Pre-Transfusion Values
1	O2 sat ≤ 90% on room air	☐ YES ☐ NO ☐ Not Performed	Pre-Txn Value:
2	PaO2FIO2 ≤ 300mm Hg	☐ YES ☐ NO ☐ Not Performed	Pre-Txn Value:
3	Chest X-ray: Bilateral infiltrates	☐ YES ☐ NO ☐ Not Performed	
4	Chest X-Ray: Widened Cardiac Silhouette (Cardiomegaly)	☐ YES ☐ NO ☐ Not Performed	
5	Elevated BNP (Provide value in pg per mL)	☐ YES ☐ NO ☐ Not Performed	Pre-Txn Value:
6	Elevated Central Venous Pressure greater than 12mm Hg (Provide values.)	☐ YES ☐ NO ☐ Not Performed	Pre-Txn Value:
7	Elevated Pulmonary Artery Pressure greater than 18 mm Hg (Provide values.)	☐ YES ☐ NO ☐ Not Performed	Pre-Txn Value:

New York Blood Center Enterprises Suspected Transfusion Related Adverse Event

8	Positive Fluid Value (in mL)	☐ YES ☐ NO ☐ Not Performed	Pre-Txn Value:
9	Transient decrease White Blood Cell Count	☐ YES ☐ NO ☐ Not Performed	Pre-Txn Value:
Post-Transfusion Diagnostics			
Diagnostic Test		Test performed?	Post-Transfusion Values
1	O2 sat ≤ 90% on room air	☐ YES ☐ NO ☐ Not Performed	Post-Txn Value:
2	PaO2FIO2 ≤ 300mm Hg	☐ YES ☐ NO ☐ Not Performed	Post-Txn Value:
3	Chest X-ray: Bilateral infiltrates	☐ YES ☐ NO ☐ Not Performed	
4	Chest X-Ray: Widened Cardiac Silhouette (Cardiomegaly)	☐ YES ☐ NO ☐ Not Performed	
5	Elevated BNP (Provide value in pg per mL)	☐ YES ☐ NO ☐ Not Performed	Post-Txn Value:
6	Elevated Central Venous Pressure greater than 12mm Hg (Provide values.)	☐ YES ☐ NO ☐ Not Performed	Post-Txn Value:
7	Elevated Pulmonary Artery Pressure greater than 18 mm Hg (Provide values.)	☐ YES ☐ NO ☐ Not Performed	Post-Txn Value:
8	Positive Fluid Value (in mL)	☐ YES ☐ NO ☐ Not Performed	Post-Txn Value:
9	Transient decrease White Blood Cell Count	☐ YES ☐ NO ☐ 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:

New York Blood Center Enterprises Suspected Transfusion Related Adverse Event

Donor HLA-HNA antibody status and identification (if performed on unit):	Donor HLA type (if available)

6	BACTERIAL CONTAMINATION

Suspected Bacterial Contamination Questions

Were the suspected units returned to the blood bank? ☐ YES ☐ NO	On reinspection does the component present any abnormalities (e.g. clumps, discoloration, hemolysis)? ☐ YES ☐ NO	Describe abnormalities (if any):

Suspect Component- Source Used: ☐ Bag ☐ Segment ☐ Not performed	Does the patient have history of fever or of other infection-related to his / her underlying medical condition? ☐ YES ☐ NO
Was the patient on antibiotics at the time of transfusion? ☐ YES ▶ ☐ NO	Specify antibiotic (if **YES**):
Is the patient currently being treated with antibiotics? ☐ YES ▶ ☐ NO	Specify antibiotic (if **YES**):
Did the patient have an absolute neutropenia count (neutrophil less than 500 per µl) prior to transfusion? ☐ YES ☐ NO	
Additional Comments:	

Suspected Bacterial Contamination Additional Testing

Gram Stain Results for unit: ☐ Negative ☐ Positive ☐ Not Done	Result (Organism):
Culture Performed on unit: ☐ Negative ☐ Positive ☐ Pending ☐ Not Done	Result (Organism):

New York Blood Center Enterprises Suspected Transfusion Related Adverse Event

Was a secondary test performed by the hospital for this component (PGD or equivalent)? ☐ YES ▶ ☐ NO	Specify test performed if **YES**:

Patient Pre-Transfusion Blood Culture ☐ Negative ☐ Positive ☐ Pending ☐ Not Done	Date of Pre-Transfusion Culture:	Result of Pre-Transfusion Culture (Organism):
Patients Post-Transfusion Blood Culture: ☐ Negative ☐ Positive ☐ Pending ☐ Not Done	Date of Post-Transfusion Culture	Result of Post-Transfusion Culture (Organism)

Signature of person reporting	Signature:	Date:

Submit the completed form to the <u>facility that shipped implicated blood</u> unit(s).

Signature Manifest

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All dates and times are in Eastern Time.

EW-FRM- 0003 rev 02 Suspected Transfusion Related Adverse Event Form

NEEC Approval

Name/Signature	Title	Date	Meaning/Reason
Betsy Jett (NY-BJETT)		23 Apr 2021, 03:42:05 PM	Approved

Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
MaryBeth Parache (NY-MPARACHE)		26 Apr 2021, 04:47:04 PM	Approved

Quick Approval

Approve Now

Name/Signature	Title	Date	Meaning/Reason
Ivette Augusto (NY-IAUGUSTO)		03 May 2021, 05:25:42 AM	Approved

Quick Approval

Approve Now

Name/Signature	Title	Date	Meaning/Reason
Ivette Augusto (NY-IAUGUSTO)		18 Oct 2021, 11:28:22 AM	Approved

Quick Approval

Approve Now

Name/Signature	Title	Date	Meaning/Reason

Ivette Augusto (NY-IAUGUSTO)		17 May 2022, 12:06:21 PM	Approved

Quick Approval

Approve Now

Name/Signature	Title	Date	Meaning/Reason
Ivette Augusto (NY-IAUGUSTO)		17 May 2022, 12:24:18 PM	Approved

Quick Approval

Approve Now

Name/Signature	Title	Date	Meaning/Reason
Ivette Augusto (NY-IAUGUSTO)		18 May 2022, 05:23:48 AM	Approved