

REPORT OF TRANSFUSION ADVERSE REACTION TO BLOOD CENTERS

INSTRUCTIONS: Send the form to ALL blood centers that provided blood components to this patient. Timely reporting is important, so that, if appropriate, the blood center may prevent the transfusion of other products from the same donor(s). [Complete areas which are not included in your internal hospital work-up and attach work-up.]

Do you suspect this reaction is the result of an attribute specific to the donor or the blood product?

☐ **Yes or suspected:**

Reaction did not result in fatality: Complete this form and forward to the blood center(s).

Reaction resulted in fatality: Complete this form, forward to the blood center(s), AND report fatality to FDA.

☐ **No:** Stop, do not report to the blood supplier.

☐ **Other:** Consult with the blood center physician.

Hospital Instructions from your Blood Provider:

For blood center use only:	Case Identification #	Date Received / / (mm/dd/yy)
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REPORTING FACILITY INFORMATION

Date Submitted / / (mm/dd/yy)

Name of Person Filling Out Form

Title of Person Filling Out Form

Telephone Number

Fax #

Email Address

Reporting Facility

Address

Blood Bank/Transfusion Services Medical Director

Phone #

PATIENT/RECIPIENT INFORMATION

Medical Record #

Name *(optional)*

Age

Date of Birth / / (mm/dd/yy) *(optional)*

Weight

Sex

Attending Physician *(optional)*

Attending's Phone # *(optional)*

Admitting or Primary Diagnosis

Indication for Transfusion

Relevant Severe Co-morbidities *(if applicable)*

Pertinent Medications

List transfusion history within 24 Hours **PRIOR** to reaction *(Attach additional sheets if necessary.)*

List transfusion history within 24 hours **AFTER** reaction

Any history of transfusion reactions *(type and date)*

Current Status at Time of Reporting:

☐ Returned to pre-transfusion status.

☐ Expired *(Transfusion related fatality)**
/ / (mm/dd/yy) *(if available)*

☐ Still requires support related to transfusion reaction.

☐ Expired *(Not transfusion related)*
/ / (mm/dd/yy) *(if available)*

☐ Other/Unknown, Specify:

* Report to FDA within 24 hours

BLOOD COMPONENT(S) INFORMATION

* Please list all components that were transfused **within the 24 hours prior to the transfusion reaction**. (Attach additional sheets if necessary.)

* For transfusion under massive transfusion protocol or rapid multiple transfusions, please give best estimate of date and time of each unit
(Attach anesthesiology record if possible).

Blood Supplier	Unit Number	Component Type or Code	Volume Transfused	Date/Time Transfusion Start	Date/Time Transfusion Stop	Was Product Modified by Hospital?
				/ / (mm/dd/yy) : (hh:mm) <input type="checkbox"/> am <input type="checkbox"/> pm	/ / (mm/dd/yy) : (hh:mm) <input type="checkbox"/> am <input type="checkbox"/> pm	<input type="checkbox"/> No <input type="checkbox"/> Yes, Specify:
				/ / (mm/dd/yy) : (hh:mm) <input type="checkbox"/> am <input type="checkbox"/> pm	/ / (mm/dd/yy) : (hh:mm) <input type="checkbox"/> am <input type="checkbox"/> pm	<input type="checkbox"/> No <input type="checkbox"/> Yes, Specify:
				/ / (mm/dd/yy) : (hh:mm) <input type="checkbox"/> am <input type="checkbox"/> pm	/ / (mm/dd/yy) : (hh:mm) <input type="checkbox"/> am <input type="checkbox"/> pm	<input type="checkbox"/> No <input type="checkbox"/> Yes, Specify:
				/ / (mm/dd/yy) : (hh:mm) <input type="checkbox"/> am <input type="checkbox"/> pm	/ / (mm/dd/yy) : (hh:mm) <input type="checkbox"/> am <input type="checkbox"/> pm	<input type="checkbox"/> No <input type="checkbox"/> Yes, Specify:
				/ / (mm/dd/yy) : (hh:mm) <input type="checkbox"/> am <input type="checkbox"/> pm	/ / (mm/dd/yy) : (hh:mm) <input type="checkbox"/> am <input type="checkbox"/> pm	<input type="checkbox"/> No <input type="checkbox"/> Yes, Specify:
				/ / (mm/dd/yy) : (hh:mm) <input type="checkbox"/> am <input type="checkbox"/> pm	/ / (mm/dd/yy) : (hh:mm) <input type="checkbox"/> am <input type="checkbox"/> pm	<input type="checkbox"/> No <input type="checkbox"/> Yes, Specify:
				/ / (mm/dd/yy) : (hh:mm) <input type="checkbox"/> am <input type="checkbox"/> pm	/ / (mm/dd/yy) : (hh:mm) <input type="checkbox"/> am <input type="checkbox"/> pm	<input type="checkbox"/> No <input type="checkbox"/> Yes, Specify:
				/ / (mm/dd/yy) : (hh:mm) <input type="checkbox"/> am <input type="checkbox"/> pm	/ / (mm/dd/yy) : (hh:mm) <input type="checkbox"/> am <input type="checkbox"/> pm	<input type="checkbox"/> No <input type="checkbox"/> Yes, Specify:
				/ / (mm/dd/yy) : (hh:mm) <input type="checkbox"/> am <input type="checkbox"/> pm	/ / (mm/dd/yy) : (hh:mm) <input type="checkbox"/> am <input type="checkbox"/> pm	<input type="checkbox"/> No <input type="checkbox"/> Yes, Specify:

REACTION INFORMATION

Date of reaction: / / (mm/dd/yy)

Time reaction started: : (hh:mm) ☐ am ☐ pm

Time transfusion started: : (hh:mm) ☐ am ☐ pm

Time transfusion stopped: : (hh:mm) ☐ am ☐ pm

Reaction Vital Signs

	Pre-Transfusion	During Reaction	Post Reaction
Date/Time	/ / (mm/dd/yy) : (hh:mm) <input type="checkbox"/> am <input type="checkbox"/> pm	/ / (mm/dd/yy) : (hh:mm) <input type="checkbox"/> am <input type="checkbox"/> pm	/ / (mm/dd/yy) : (hh:mm) <input type="checkbox"/> am <input type="checkbox"/> pm
Temperature	°C/°F	°C/°F	°C/°F
Blood Pressure (Systolic)	mm Hg	mm Hg	mm Hg
Blood Pressure (Diastolic)	mm Hg	mm Hg	mm Hg
Pulse	bpm	bpm	bpm
Respiratory Rate	bpm	bpm	bpm
O ₂ Sat	%	%	%

Symptoms/Signs at time of reaction – Check all that apply.

- | | | |
|--|---|--|
| <input type="checkbox"/> Abdominal pain/cramps [1,4]
<input type="checkbox"/> Angioedema [1]
<input type="checkbox"/> Anxiety [1]
<input type="checkbox"/> Arrhythmia [1]
<input type="checkbox"/> Back pain [4]
<input type="checkbox"/> Cardiac arrest [1]
<input type="checkbox"/> Chest pain [4]
<input type="checkbox"/> Chest tightness [1, 3]
<input type="checkbox"/> Chills/Rigors [4]
<input type="checkbox"/> Cough [3, 4]
<input type="checkbox"/> Cyanosis [1, 2, 3]
<input type="checkbox"/> Diarrhea [1]
<input type="checkbox"/> DIC [4] | <input type="checkbox"/> Dyspnea [1, 2, 3, 4]
<input type="checkbox"/> Edema – pulmonary [2,3]
<input type="checkbox"/> Edema – Pedal [3]
<input type="checkbox"/> Erythema [1]
<input type="checkbox"/> Fever [2, 4]
<input type="checkbox"/> Flushing [1]
<input type="checkbox"/> Headache [3, 4]
<input type="checkbox"/> Hoarseness/Stridor [1]
<input type="checkbox"/> Hypertension [2, 3]
<input type="checkbox"/> Hypotension [1, 2, 4]
<input type="checkbox"/> Hypoxemia [2, 3]
<input type="checkbox"/> Impending doom [1]
<input type="checkbox"/> Jugular venous distension [3] | <input type="checkbox"/> Loss of consciousness [1]
<input type="checkbox"/> Nausea/Vomiting [1, 4]
<input type="checkbox"/> Oliguria [4]
<input type="checkbox"/> Orthopnea [3]
<input type="checkbox"/> Pain at infusion site [4]
<input type="checkbox"/> Pruritis [1]
<input type="checkbox"/> Shock [1, 4]
<input type="checkbox"/> Substernal pain [1]
<input type="checkbox"/> Tachycardia [1, 2, 3, 4]
<input type="checkbox"/> Tachypnea [2,3]
<input type="checkbox"/> Urticaria [1]
<input type="checkbox"/> Wheezing [1, 4]
<input type="checkbox"/> Widened pulse pressure [3] |
|--|---|--|

Allergic/Anaphylactic [1] | TRALI [2] | TACO [3] | Septic Transfusion Reaction [4]

Suspected Adverse Reaction: Assign priority if more than one possibility*

- | | | | |
|---|--|--|--|
| <input type="checkbox"/> Allergic/Anaphylaxis | <input type="checkbox"/> Transfusion-related acute lung injury (TRALI) | <input type="checkbox"/> Septic transfusion reaction | <input type="checkbox"/> Other, Specify: |
|---|--|--|--|

Additional information: (If more than one possibility, assign priority.)

* Please refer to the **National Healthcare Safety Network Biovigilance Component Hemovigilance Module Surveillance Protocol** for complete definitions.

PULMONARY-ALLERGIC-ANAPHYLACTIC REACTION INFORMATION

Risk factors for Acute Lung Injury – Check all that apply.

<input type="checkbox"/> Acute Respiratory Distress Syndrome (ARDS) <input type="checkbox"/> Aspiration <input type="checkbox"/> Pneumonia <input type="checkbox"/> Toxic inhalation <input type="checkbox"/> Lung contusion <input type="checkbox"/> Near drowning <input type="checkbox"/> Pulmonary hemorrhage	<input type="checkbox"/> Severe sepsis <input type="checkbox"/> Shock <input type="checkbox"/> Multiple trauma <input type="checkbox"/> Burn <input type="checkbox"/> Acute pancreatitis <input type="checkbox"/> Cardiopulmonary bypass <input type="checkbox"/> Drug overdose <input type="checkbox"/> Volume overload <input type="checkbox"/> Renal failure	<input type="checkbox"/> Upper airway obstruction <input type="checkbox"/> Diffuse alveolar damage <input type="checkbox"/> Chemotherapy <input type="checkbox"/> Amiodarone <input type="checkbox"/> Disseminated intravascular coagulation <input type="checkbox"/> Radiation to thorax <input type="checkbox"/> Massive blood transfusion
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Additional comments (Other risk factors)

Diagnostics – Check box and/or enter values.

	Pre-Transfusion			Pre-Tx Values	Post-Transfusion			Post-Tx Values
O₂ sat ≤ 90% on room air	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not Done		<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not Done	
PaO₂/FiO₂ ≤ 300 mm Hg	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not Done		<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not Done	
Chest X-ray: Bilateral infiltrates	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not Done		<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not Done	
Chest X-ray: Widened cardiac silhouette (cardiomegaly)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not Done		<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not Done	
Elevated BNP (Provide value in pg/mL.) <input type="checkbox"/> BNP <input type="checkbox"/> NT-proBNP	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not Done		<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not Done	
Elevated Central Venous Pressure greater than 12 mm Hg (Provide values.)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not Done		<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not Done	
Elevated Pulmonary Artery Pressure greater than 18 mm Hg (Provide values.)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not Done		<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not Done	
Positive Fluid Balance (in mL) (Attach patient I/O report if available)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not Done		<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not Done	
Transient decrease White Blood Cell Count	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not Done		<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not Done	

Treatment and Clinical Course		
	Treatment (Check yes, if treatment was administered.)	Response to Treatment (Check yes, if patient improved following 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
Vasopressors	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes
Other (specify):	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes

Additional comments *(Attach additional clinical information if available.)*

If TRALI is suspected, please save an EDTA (purple-top) patient sample.

Recipient HLA type:

Recipient HNA type:

Recipient HLA/HNA antibody status:

Donor HLA/HNA antibody result (if performed on unit):

Donor HLA type (if available):

SUSPECTED BACTERIAL CONTAMINATION

Were the suspect components returned to the blood bank? ☐ No ☐ Yes

On repeat visual inspection, does the component reveal any abnormalities (e.g. clumps, discoloration, hemolysis)?

☐ No ☐ Yes: Describe:

☐ Unevaluable

Suspect component – Source used: ☐ Bag ☐ Segment ☐ Not done

Gram stain performed:

☐ Negative ☐ Positive ☐ Not done

Result (organism identified, if positive):

Culture performed:

☐ Negative ☐ Positive ☐ Pending ☐ Not done

Result (organism identified, if positive):

Was a secondary test performed by the hospital for this component (PGD or equivalent)?

☐ No ☐ Yes, Specify:

Patient's pre-transfusion blood culture: ☐ Negative ☐ Positive ☐ Pending ☐ Not done

Date/Time: / / (mm/dd/yy)

: (hh:mm) ☐ am ☐ pm

Result (organism identified, if positive):

Patient's post-transfusion blood culture result: ☐ Negative ☐ Positive ☐ Pending ☐ Not done

Date/Time: / / (mm/dd/yy)

: (hh:mm) ☐ am ☐ pm

Result (organism identified, if positive):

Does the patient have history of fever or other infection related to his/her underlying medical condition? ☐ No ☐ Yes

Was the patient on antibiotics at the time of transfusion? ☐ No ☐ Yes, Name:

Is the patient currently being treated with antibiotics? ☐ No ☐ Yes, Name:

Did the patient have an absolute neutropenia (neutrophil count less than 500 per μ l) prior to transfusion? ☐ No ☐ Yes

Comments:

FOR TRANSFUSION MEDICAL DIRECTOR REVIEW

Final interpretation and classification*

Reaction

☐ Allergic/Anaphylactic ☐ TRALI ☐ TACO ☐ Septic Transfusion Reaction ☐ Other:

Case definition criteria

☐ Definitive ☐ Probable ☐ Possible

Severity

☐ Non-severe ☐ Severe ☐ Life Threatening ☐ Death

Imputability

☐ Definite ☐ Probable ☐ Possible ☐ Doubtful ☐ Ruled out ☐ Not Determined

Notes

Transfusion Medical Director contact/phone/email

Transfusion Medical Director (or designee) signature

* Please refer to the **National Healthcare Safety Network Biovigilance Component Hemovigilance Module Surveillance Protocol** for complete definitions.

FOR BLOOD CENTER USE

Final interpretation and classification*

Reaction	<input type="checkbox"/> Allergic/Anaphylactic <input type="checkbox"/> TRALI <input type="checkbox"/> TACO <input type="checkbox"/> Septic Transfusion Reaction <input type="checkbox"/> Other:
Case definition criteria	<input type="checkbox"/> Definitive <input type="checkbox"/> Probable <input type="checkbox"/> Possible
Severity	<input type="checkbox"/> Non-severe <input type="checkbox"/> Severe <input type="checkbox"/> Life Threatening <input type="checkbox"/> Death
Imputability	<input type="checkbox"/> Definite <input type="checkbox"/> Probable <input type="checkbox"/> Possible <input type="checkbox"/> Doubtful <input type="checkbox"/> Ruled out <input type="checkbox"/> Not Determined
Notes	

Blood Center contact/phone/email

* Please refer to the **National Healthcare Safety Network Biovigilance Component Hemovigilance Module Surveillance Protocol** for complete definitions.