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:

Instructions: Please complete the following fillable form and submit to LifeStream, Medical Surveillance by:

E-mail to: MedicalSurveillance@LStream.org (preferred) or
FAX to: (909) 386-6817

If you have any questions please call (800) 879-4484 ext 655

Please attach the following:
• Copy of completed hospital internal Transfusion Reaction Work-up Form
• Copy of pre- and post-transfusion chest x-ray reports for suspected TRALI reactions
• Copy of culture results for suspected sepsis cases
• Copy of applicable Admission Note, Physician notes regarding reaction, Discharge Note

Frequently Asked Questions
Q 1: What is the purpose of the form?
A 1: This form is meant to open the conversation between a hospital and its blood suppliers about a transfusion reaction. The intent is to include sufficient information for the blood supplier and hospital to investigate the reaction. The form is designed only for reactions suspected to be attributable to blood product(s), in particular reactions for which there is a potential blood supplier's intervention possible. Examples of these types of reactions include TRALI, septic transfusion reactions, etc.

Cases of TACO do not need to be reported to your blood suppliers. Data elements associated with TACO are provided to assist the differentiation between various pulmonary reactions.

Q 2: Why is the form so long?
A 2: We included space to capture relevant information for the investigation of the reaction and the associated blood components. In order to make this a fillable form, there is more white space, so it may appear much longer.

Q 3: Which Sections do I need to complete?
A 3: For all reactions you need to complete
• Reporting Facility Information
• Patient/Recipient Information
• Blood Component Information
• Reaction Information
• Section that is specific to the reaction type—either Pulmonary/Allergic/Anaphylactic or Suspected Bacterial Contamination

Q 4: When should I send this form to my blood suppliers?
A 4: The form should be submitted as soon as possible so that the blood collector can evaluate how to handle donors or any co-components that may cause patient harm.

NOTE: Suspected Transfusion Associated Viral Infections should be reported on the "Report of Suspected Transfusion-Aquired Infection" Form (MSU-00272.F4).

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

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) ☐ am ☐ pm	/ / (mm/dd/yy) : (hh:mm) ☐ am ☐ pm	☐ No ☐ Yes, Specify:
				/ / (mm/dd/yy) : (hh:mm) ☐ am ☐ pm	/ / (mm/dd/yy) : (hh:mm) ☐ am ☐ pm	☐ No ☐ Yes, Specify:
				/ / (mm/dd/yy) : (hh:mm) ☐ am ☐ pm	/ / (mm/dd/yy) : (hh:mm) ☐ am ☐ pm	☐ No ☐ Yes, Specify:
				/ / (mm/dd/yy) : (hh:mm) ☐ am ☐ pm	/ / (mm/dd/yy) : (hh:mm) ☐ am ☐ pm	☐ No ☐ Yes, Specify:
				/ / (mm/dd/yy) : (hh:mm) ☐ am ☐ pm	/ / (mm/dd/yy) : (hh:mm) ☐ am ☐ pm	☐ No ☐ Yes, Specify:
				/ / (mm/dd/yy) : (hh:mm) ☐ am ☐ pm	/ / (mm/dd/yy) : (hh:mm) ☐ am ☐ pm	☐ No ☐ Yes, Specify:
				/ / (mm/dd/yy) : (hh:mm) ☐ am ☐ pm	/ / (mm/dd/yy) : (hh:mm) ☐ am ☐ pm	☐ No ☐ Yes, Specify:
				/ / (mm/dd/yy) : (hh:mm) ☐ am ☐ pm	/ / (mm/dd/yy) : (hh:mm) ☐ am ☐ pm	☐ No ☐ Yes, Specify:
				/ / (mm/dd/yy) : (hh:mm) ☐ am ☐ pm	/ / (mm/dd/yy) : (hh:mm) ☐ am ☐ pm	☐ No ☐ 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) ☐ am ☐ pm	/ / (mm/dd/yy) : (hh:mm) ☐ am ☐ pm	/ / (mm/dd/yy) : (hh:mm) ☐ am ☐ 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.

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

☐ Allergic/Anaphylaxis	☐ Transfusion-related acute lung injury (TRALI)	☐ Septic transfusion reaction	☐ 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.

- ☐ Acute Respiratory Distress Syndrome (ARDS)
- ☐ Aspiration
- ☐ Pneumonia
- ☐ Toxic inhalation
- ☐ Lung contusion
- ☐ Near drowning
- ☐ Pulmonary hemorrhage
- ☐ Severe sepsis
- ☐ Shock
- ☐ Multiple trauma
- ☐ Burn
- ☐ Acute pancreatitis
- ☐ Cardiopulmonary bypass
- ☐ Drug overdose
- ☐ Volume overload
- ☐ Renal failure
- ☐ Upper airway obstruction
- ☐ Diffuse alveolar damage
- ☐ Chemotherapy
- ☐ Amiodarone
- ☐ Disseminated intravascular coagulation
- ☐ Radiation to thorax
- ☐ Massive blood transfusion

Additional comments *(Other risk factors)*

Diagnostics – Check box and/or enter values.

	Pre-Transfusion			Pre-Tx Values	Post-Transfusion			Post-Tx Values
O_2 sat ≤ 90% on room air	☐ Yes	☐ No	☐ Not Done		☐ Yes	☐ No	☐ Not Done	
PaO_2/FiO_2 ≤ 300 mm Hg	☐ Yes	☐ No	☐ Not Done		☐ Yes	☐ No	☐ Not Done	
Chest X-ray: Bilateral infiltrates	☐ Yes	☐ No	☐ Not Done		☐ Yes	☐ No	☐ Not Done	
Chest X-ray: Widened cardiac silhouette (cardiomegaly)	☐ Yes	☐ No	☐ Not Done		☐ Yes	☐ No	☐ Not Done	
Elevated **BNP** *(Provide value in pg/mL.)* ☐ BNP ☐ NT-proBNP	☐ Yes	☐ No	☐ Not Done		☐ Yes	☐ No	☐ Not Done	
Elevated **Central Venous Pressure** greater than 12 mm Hg *(Provide values.)*	☐ Yes	☐ No	☐ Not Done		☐ Yes	☐ No	☐ Not Done	
Elevated **Pulmonary Artery Pressure** greater than 18 mm Hg *(Provide values.)*	☐ Yes	☐ No	☐ Not Done		☐ Yes	☐ No	☐ Not Done	
Positive Fluid Balance *(in mL)* *(Attach patient I/O report if available)*	☐ Yes	☐ No	☐ Not Done		☐ Yes	☐ No	☐ Not Done	
Transient decrease **White Blood Cell Count**	☐ Yes	☐ No	☐ Not Done		☐ Yes	☐ No	☐ Not Done	

Treatment and Clinical Course

	Treatment *(Check yes, if treatment was administered.)*	**Response to Treatment** *(Check yes, if patient improved following 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
Vasopressors	☐ Yes	☐ Yes
Other (specify):	☐ Yes	☐ 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 µl) 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	

Tranfusion Medical Director contact/phone/email

Tranfusion 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	☐ Allergic/Anaphylactic ☐ TRALI ☐ TACO ☐ Septic Transfusion Reaction ☐ Other:
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Imputability	☐ Definite ☐ Probable ☐ Possible ☐ Doubtful ☐ Ruled out ☐ 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.