REPORT OF ADVERSE TRANSFUSION REACTION TO BLOOD SUPPLIERS

INSTRUCTIONS: Send the form to ALL blood suppliers that provided blood components to this patient. Timely reporting is important, so that, if appropriate, the blood supplier 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 supplier(s).
Reaction resulted in fatality: Complete this form, forward to the blood supplier(s), AND report fatality to FDA.*

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

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

Additional Blood Supplier Instructions for the Hospital Transfusion Service, as applicable:

GENERAL INSTRUCTIONS

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 and TACO reactions
- Copy of Culture and pending tests *(when available)* for suspected sepsis cases
- Copy of applicable Admission Note, Physician notes regarding reaction, Discharge Note
- Copy of allergy and medication list for suspected allergy reactions.

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

* Report to FDA as soon as possible.

REPORTING FACILITY INFORMATION

Date Submitted / / **(mm/dd/yy)**	Reporting Facility	
Name of Person Filling Out Form		Title
Facility Address		
Telephone Number	Fax #	Email
Transfusion Services Medical Director		
Transfusion Services Medical Director Email		Phone #

PATIENT/RECIPIENT INFORMATION

Medical Record #	Name *(optional)*
Age	Date of Birth / / **(mm/dd/yy)** *(optional)*
Weight	Sex
Attending Physician *(optional)*	Attending Physician'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 prior history of transfusion reactions *(type and date)*

Recipient Blood Type

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 as soon as possible.*

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	ABO Blood Type	Volume Transfused *(approximate in mL)*	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/Time Transfusion Started: / / (mm/dd/yy) : (hh:mm) ☐ am ☐ pm
Date/Time Reaction Started: / / (mm/dd/yy) : (hh:mm) ☐ am ☐ pm
Date/Time Transfusion Stopped: / / (mm/dd/yy) : (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	rpm	rpm	rpm
O_2 Sat	%	%	%

Symptoms/Signs at Time of Reaction – Check all that apply.

- ☐ **Abdominal pain/Cramps**
- ☐ **Angioedema**
- ☐ **Anxiety**
- ☐ **Arrythmia**
- ☐ **Back pain**
- ☐ **Cardiac arrest**
- ☐ **Chest pain**
- ☐ **Chest tightness**
- ☐ **Chills/Rigors**
- ☐ **Cough**
- ☐ **Cyanosis**
- ☐ **Diarrhea**
- ☐ **Disseminated Intravascular Coagulation**
- ☐ **Dyspnea**
- ☐ **Edema – Pulmonary**
- ☐ **Edema – Pedal**
- ☐ **Erythema**
- ☐ **Fever**
- ☐ **Flushing**
- ☐ **Headache**
- ☐ **Hoarseness/Stridor**
- ☐ **Hypertension**
- ☐ **Hypotension**
- ☐ **Hypoxemia**
- ☐ **Impending doom**
- ☐ **Jugular venous distension**
- ☐ **Loss of consciousness**
- ☐ **Nausea/Vomiting**
- ☐ **Oliguria**
- ☐ **Orthopnea**
- ☐ **Pain at infusion site**
- ☐ **Pruritis**
- ☐ **Shock**
- ☐ **Substernal pain**
- ☐ **Tachycardia**
- ☐ **Tachypnea**
- ☐ **Urticaria**
- ☐ **Wheezing**
- ☐ **Widened pulse pressure**

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.

† Attach allergy and medication list
‡ Attach chest x-ray report
§ Please forward results of culture and pending tests when available

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
- ☐ COVID-19 related respiratory disease

Additional comments *(Other risk factors)*

Diagnostics – Check box and/or enter values.

	Pre-Transfusion					Post-Transfusion				
	Date and Time	**Yes/No/ Not Done**			**Pre-Tx Values**	**Date and Time**	**Yes/No/ Not Done**			**Post-Tx Values**
O_2 sat ≤ 90% on room air	/ / **(mm/dd/yy)** : **(hh:mm)** ☐ **am** ☐ **pm**	☐ Yes	☐ No	☐ Not Done		/ / **(mm/dd/yy)** : **(hh:mm)** ☐ **am** ☐ **pm**	☐ Yes	☐ No	☐ Not Done	
PaO_2/FiO_2 ≤ 300 mm Hg	/ / **(mm/dd/yy)** : **(hh:mm)** ☐ **am** ☐ **pm**	☐ Yes	☐ No	☐ Not Done		/ / **(mm/dd/yy)** : **(hh:mm)** ☐ **am** ☐ **pm**	☐ Yes	☐ No	☐ Not Done	
Chest X-ray: Bilateral infiltrates *(Attach chest x-ray report if available)*	/ / **(mm/dd/yy)** : **(hh:mm)** ☐ **am** ☐ **pm**	☐ Yes	☐ No	☐ Not Done		/ / **(mm/dd/yy)** : **(hh:mm)** ☐ **am** ☐ **pm**	☐ Yes	☐ No	☐ Not Done	
Chest X-ray: Widened cardiac silhouette (cardiomegaly)	/ / **(mm/dd/yy)** : **(hh:mm)** ☐ **am** ☐ **pm**	☐ Yes	☐ No	☐ Not Done		/ / **(mm/dd/yy)** : **(hh:mm)** ☐ **am** ☐ **pm**	☐ Yes	☐ No	☐ Not Done	
Elevated **BNP** *(Provide value in pg/mL)* ☐ BNP ☐ NT-proBNP	/ / **(mm/dd/yy)** : **(hh:mm)** ☐ **am** ☐ **pm**	☐ Yes	☐ No	☐ Not Done		/ / **(mm/dd/yy)** : **(hh:mm)** ☐ **am** ☐ **pm**	☐ Yes	☐ No	☐ Not Done	
Positive Fluid Balance *(in mL) (Attach patient I/O report if available)*	/ / **(mm/dd/yy)** : **(hh:mm)** ☐ **am** ☐ **pm**	☐ Yes	☐ No	☐ Not Done		/ / **(mm/dd/yy)** : **(hh:mm)** ☐ **am** ☐ **pm**	☐ Yes	☐ No	☐ Not Done	
White Blood Cell Count: Transient fluctuation	/ / **(mm/dd/yy)** : **(hh:mm)** ☐ **am** ☐ **pm**	☐ Yes	☐ No	☐ Not Done		/ / **(mm/dd/yy)** : **(hh:mm)** ☐ **am** ☐ **pm**	☐ Yes	☐ No	☐ Not Done	
Pertinent lab results	/ / **(mm/dd/yy)** : **(hh:mm)** ☐ **am** ☐ **pm**	☐ Yes	☐ No	☐ Not Done		/ / **(mm/dd/yy)** : **(hh:mm)** ☐ **am** ☐ **pm**	☐ 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
Room air	☐ Yes	☐ Yes
Nasal cannula *(specify flow rate in liters/minute)*	☐ Yes	☐ Yes
Noninvasive positive pressure ventilation *(Specify cm H_2O)*	☐ Yes	☐ Yes
Other *(specify)*:	☐ Yes	☐ Yes

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

If TRALI is suspected, please save an EDTA (purple or pink 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 for culture: ☐ 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 (Point of release bacterial detection test 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 SERVICES MEDICAL DIRECTOR REVIEW

Provisional 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 Services Medical Director contact/phone/email

Tranfusion Services Medical Director (or designee) signature

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

FOR BLOOD SUPPLIER USE

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 *(Attach additional reports, if available)*

Blood Supplier contact/phone/email

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