***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.**

|  |  |
| --- | --- |
| **Community Blood Centers- Kansas City*** 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
 | **New York Blood Center**Special Donor Services Department* Phone: 800-688-0900
* Fax: 212-288-8464
 |
| **Blood Bank of Delmarva**Submit reports through Blood Hub. If not available, send report to:Reference Laboratory * Fax: 302-709-6155
* Then call 302-737-8405 ext. 716
 | **Rhode Island Blood Center**Laboratory Supervisor* Phone: 401-453-8374
* Fax: 401-248-5750
 |
| **Innovative Blood Resources**Memorial Blood CentersNebraska Community Blood BankPhysician Services Donor Advocates* Phone 651-332-7287, Fax 651-332-7001
 |  |

|  |  |
| --- | --- |
| 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 ▶ |  |

|  |  |
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| 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:  |
|  |

|  |
| --- |
| ***(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 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) |

|  |  |
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| 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: |
|  |  |

|  |  |  |
| --- | --- | --- |
| 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*) |
|  |
| 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: |
|  |  |
| 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 ⯆ |
|[ ]  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 | Pre-Txn Value: |
|  |  |  [ ]  NO |  |
|  |  |  [ ]  Not Performed |  |
| 2 | PaO2FIO2 ≤ 300mm Hg |  [ ]  YES | Pre-Txn Value: |
|  |  |  [ ]  NO |  |
|  |  |  [ ]  Not Performed |  |
| 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 | Pre-Txn Value: |
|  |  |  [ ]  NO |  |
|  |  |  [ ]  Not Performed |  |
| 6 | Elevated Central Venous Pressure greater than 12mm Hg (Provide values.) |  [ ]  YES | Pre-Txn Value: |
|  |  |  [ ]  NO |  |
|  |  |  [ ]  Not Performed |  |
| 7 | Elevated Pulmonary Artery Pressure greater than 18 mm Hg (Provide values.) |  [ ]  YES | Pre-Txn Value: |
|  |  |  [ ]  NO |  |
|  |  |  [ ]  Not Performed |  |
| 8 | Positive Fluid Value (in mL) |  [ ]  YES | Pre-Txn Value: |
|  |  |  [ ]  NO |  |
|  |  |  [ ]  Not Performed |  |
| 9 | Transient decrease White Blood Cell Count |  [ ]  YES | Pre-Txn Value: |
|  |  |  [ ]  NO |  |
|  |  |  [ ]  Not Performed |  |
| **Post-Transfusion Diagnostics** |
| Diagnostic Test | Test performed? | Post-Transfusion Values |
| 1 | O2 sat ≤ 90% on room air |  [ ]  YES | Post-Txn Value: |
|  |  |  [ ]  NO |  |
|  |  |  [ ]  Not Performed |  |
| 2 | PaO2FIO2 ≤ 300mm Hg |  [ ]  YES | Post-Txn Value: |
|  |  |  [ ]  NO |  |
|  |  |  [ ]  Not Performed |  |
| 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 | Post-Txn Value: |
|  |  |  [ ]  NO |  |
|  |  |  [ ]  Not Performed |  |
| 6 | Elevated Central Venous Pressure greater than 12mm Hg (Provide values.) |  [ ]  YES | Post-Txn Value: |
|  |  |  [ ]  NO |  |
|  |  |  [ ]  Not Performed |  |
| 7 | Elevated Pulmonary Artery Pressure greater than 18 mm Hg (Provide values.) |  [ ]  YES | Post-Txn Value: |
|  |  |  [ ]  NO |  |
|  |  |  [ ]  Not Performed |  |
| 8 | Positive Fluid Value (in mL) |  [ ]  YES | Post-Txn Value: |
|  |  |  [ ]  NO |  |
|  |  |  [ ]  Not Performed |  |
| 9 | Transient decrease White Blood Cell Count |  [ ]  YES | Post-Txn Value: |
|  |  |  [ ]  NO |  |
|  |  |  [ ]  Not Performed |  |
| **If TRALI is diagnosed, please provide the following:** |
| Recipient HLA Type: | Recipient HNA Type: | Recipient HLA-HNA antibody status and identification: |
|  |  |  |
| Donor HLA-HNA antibody status and identification (if performed on unit): | Donor HLA type (if available) |
|  |  |

|  |  |
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| 6 | BACTERIAL CONTAMINATION |
| **Suspected Bacterial Contamination Questions** |
| Were the suspected units returned to the blood bank? | On reinspection does the component present any abnormalities (e.g. clumps, discoloration, hemolysis)? | Describe abnormalities (if any): |
|  [ ]  YES |  [ ]  YES |
|  [ ]  NO |  [ ]  NO |
| Suspect Component- Source Used: | Does the patient have history of fever or of other infection-related to his / her underlying medical condition? |
|  [ ]  Bag |
|  [ ]  Segment |  [ ]  YES |
|  [ ]  Not performed |  [ ]  NO |
| Was the patient on antibiotics at the time of transfusion? | Specify antibiotic (if **YES**): |
|  [ ]  YES ▶ |
|  [ ]  NO |
| Is the patient currently being treated with antibiotics? | Specify antibiotic (if **YES**): |
|  [ ]  YES ▶ |
|  [ ]  NO |
| 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: | Result (Organism): |
|  [ ]  Negative |
|  [ ]  Positive  |
|  [ ]  Not Done |
| Culture Performed on unit: | Result (Organism): |
|  [ ]  Negative |
|  [ ]  Positive  |
|  [ ]  Pending |
|  [ ]  Not Done |
| Was a secondary test performed by the hospital for this component (PGD or equivalent)? | Specify test performed if **YES**: |
|  [ ]  YES ▶ |
|  [ ]  NO |
| Patient Pre-Transfusion Blood Culture | Date of Pre-Transfusion Culture: | Result of Pre-Transfusion Culture (Organism): |
|  [ ]  Negative |
|  [ ]  Positive  |
|  [ ]  Pending |
|  [ ]  Not Done |
| Patients Post-Transfusion Blood Culture: | Date of Post-Transfusion Culture | Result of Post-Transfusion Culture (Organism) |
|  [ ]  Negative |
|  [ ]  Positive  |
|  [ ]  Pending |
|  [ ]  Not Done |

|  |  |  |
| --- | --- | --- |
| **Signature of person reporting** | Signature: | Date: |
|  |  |

**Submit the completed form to the facility that shipped implicated blood unit(s).**