***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](mailto: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](mailto:QAGroupALL@cbckc.org) * Post Transfusion Disease- Fax to Donor Notification at 816-277-0785 or email to [TherapeuticCollectionServices@cbckc.org](mailto: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 Centers  Nebraska Community Blood Bank  Physician 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 ▶ | |  | | | | | | |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 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) |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 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: | | |
|  | |  | | |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 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) | | | | |
|  | | | | | | |  | | | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 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).**