**Hemovigilance Module**

**Adverse Reaction**

\*Required for saving

|  |  |
| --- | --- |
| \*Facility ID#: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | NHSN Adverse Reaction #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| [ ]  Share report with FDA |
| **Patient Information** |
| \*Patient ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \*Gender: | [ ]  M | [ ]  F | [ ]  Other | \*Date of Birth: \_\_ \_\_/\_\_ \_\_/\_\_ \_\_ \_\_ \_\_ |
| Social Security #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Secondary ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Medicare #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Last Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | First Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Middle Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Ethnicity | [ ]  Hispanic or Latino | [ ]  Not Hispanic or Not Latino |
| Race | [ ]  American Indian/Alaska Native | [ ]  Asian | [ ]  Black or African American |
| [ ]  Native Hawaiian/Other Pacific Islander | [ ]  White |
| \*Blood Group: | [ ]  A- | [ ]  A+ | [ ]  B- | [ ] B+ | [ ]  AB- | [ ]  AB+ | [ ]  O- | [ ]  O+ | [ ]  Type and crossmatch not done |
| \*Primary underlying reason for transfusion: | [ ]  Coagulopathy | [ ]  Genetic Disorder | [ ]  Hematology Disorder |
| [ ]  Hemolysis | [ ]  Internal Bleeding | [ ]  Malignancy | [ ]  Medical | [ ]  Surgery | [ ]  Unknown |
| [ ]  Other (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Reaction Details** |
| \*Date reaction occurred: \_\_ \_\_/\_\_ \_\_/\_\_ \_\_ \_\_ \_\_ |
| \*Time reaction occurred: \_\_ \_\_:\_\_ \_\_ (HH:MM) | [ ]  Time unknown |
| \*Facility location where patient was transfused: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \*Is this reaction associated with an incident? | [ ]  Yes | [ ]  No | If Yes, Incident #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \*Signs and symptoms, laboratory: (check all that apply) |
| **Cardiovascular:** | **Cutaneous:** | **Pain:** |
| [ ]  Blood pressure decrease | [ ]  Edema | [ ]  Abdominal pain |
| [ ]  Shock | [ ]  Flushing | [ ]  Back pain |
| **Hemolysis/Hemorrhage** | [ ]  Jaundice | [ ]  Flank pain |
| [ ]  Disseminated intravascular coagulation | [ ]  Other rash | [ ]  Infusion site pain |
| [ ]  Hemoglobinemia | [ ]  Pruritus (itching) | **Respiratory:** |
| [ ]  Positive antibody screen | [ ]  Urticaria (hives) | [ ]  Bilateral infiltrates on chest x-ray |
| **Generalized:** | **Renal:** | [ ]  Bronchospasm |
| [ ]  Chills/rigors | [ ]  Hematuria | [ ]  Cough |
| [ ]  Fever | [ ]  Hemoglobinuria | [ ]  Hypoxemia |
| [ ]  Nausea/vomiting | [ ]  Oliguria | [ ]  Shortness of breath |
| [ ]  Other: (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Assurance of Confidentiality:** The voluntarily provided information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with Sections 304, 306 and 308(d) of the Public Health Service Act (42 USC 242b, 242k, and 242m(d)).Public reporting burden of this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC, Reports Clearance Officer, 1600 Clifton Rd., MS D-74, Atlanta, GA 30333 ATTN: PRA (0920-0666). |
| **Investigation Results (Use case definition criteria in protocol.)** |
| \*Adverse reaction: (check one) |
| [ ]  Allergic reaction, including anaphylaxis |
| [ ]  Acute hemolytic transfusion reaction (AHTR) |
| [ ]  Immune | Antibody: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | [ ]  Non-immune (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| [ ]  Delayed hemolytic transfusion reaction (DHTR) |
| [ ]  Immune | Antibody: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | [ ]  Non-immune (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| [ ]  Delayed serologic transfusion reaction (DSTR) | Antibody(ies): | \_\_\_\_ | \_\_\_\_ | \_\_\_\_ | \_\_\_\_ | \_\_\_\_ | \_\_\_\_ |
| [ ]  Febrile non-hemolytic transfusion reaction (FNHTR) |
| [ ]  Hypotensive transfusion reaction |
| [ ]  Infection  |
| Was a test to detect a specific pathogen performed on the recipient post-transfusion? |
| [ ]  Yes | [ ]  No | If Yes, positive or reactive results? | [ ]  Yes | [ ]  No |
| Org1 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Org2 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Org3 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Was a test to detect a specific pathogen performed on the donor post-donation? |
| [ ]  Yes | [ ]  No | If Yes, positive or reactive results? | [ ]  Yes | [ ]  No |
| Org1 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Org2 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Org3 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Was a test to detect a specific pathogen performed on the unit post-transfusion? (i.e., culture, serology, NAT) |
| [ ]  Yes | [ ]  No | If Yes, positive or reactive results? | [ ]  Yes | [ ]  No |
| Org1 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Org2 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Org3 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| [ ]  Post transfusion purpura (PTP) |
| [ ]  Transfusion associated circulatory overload (TACO) |
| [ ]  Transfusion associated dyspnea (TAD) |
| [ ]  Transfusion associated graft vs. host disease (TA-GVHD) |
| Did patient receive non-irradiated blood product(s) in the two months preceding the reaction? | [ ]  Yes | [ ]  No |
| [ ]  Transfusion related acute lung injury (TRALI) |
| Antibody studies performed: (optional) |
|

|  |  |  |  |
| --- | --- | --- | --- |
|  | Not Done | Negative | Test result positive |
| Cognate or cross reacting antigen present | No cognate or cross reacting antigen present | Not tested for cognate antigen |
| Donor or unit HLA specificity | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Donor or unit HNA specificity | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Recipient HLA specificity | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Recipient HNA specificity | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |

 |
| [ ]  Unknown |
| [ ]  Other (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \*Case definition criteria: | [ ]  Definitive | [ ]  Probable | [ ]  Possible | [ ]  N/A |
| \*Severity: | [ ]  Non-severe | [ ]  Severe | [ ]  Life-threatening | [ ]  Death | [ ]  Not determined |
| \*Imputability: | [ ]  Definite | [ ]  Probable | [ ]  Possible | [ ]  Doubtful | [ ]  Ruled Out | [ ]  Not determined |
| **Outcome** |
| \*Outcome:  | [ ]  Death+ | [ ]  Major or long-term sequelae | [ ]  Minor or no sequelae | [ ]  Not determined |
| Date of Death: \_\_ \_\_/\_\_ \_\_/\_\_ \_\_ \_\_ \_\_  | **+Deaths attributable to transfusion must be reported to FDA.** |
| ^If recipient died, relationship of transfusion to death: |
| [ ]  Definite | [ ]  Probable | [ ]  Possible | [ ]  Doubtful | [ ]  Ruled Out | [ ]  Not determined |
| **Component Details (Use worksheet on page 4 for additional units.)** |
| \*Was a particular unit implicated in (i.e., responsible for) the adverse reaction? | [ ]  Yes | [ ]  No | [ ]  N/A |
| \*Transfusion **End** Date/Time  | \*Component code (check system used) | \*# of units | ^Unit number *Required for TRALI, GVHD, Infection* | \*Unit expiration Date/Time  | \*Blood group of unit | Implicated in the adverse reaction? |
| **^IMPLICATED UNIT** |
| \_\_\_\_/\_\_\_\_/\_\_\_\_\_\_ | [ ]  ISBT-128 | 1 | \_\_ \_\_ \_\_ \_\_ \_\_ | \_\_\_/\_\_\_/\_\_\_\_\_\_ | [ ]  A- | [ ]  A+ | [ ]  B- | Y |
|  | [ ]  Codabar |  | \_\_ \_\_ |  |  |  |  |  |
| \_\_\_ \_\_\_:\_\_\_ \_\_\_ | \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ |  | \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ | \_\_\_ \_\_\_:\_\_\_ \_\_\_ | [ ] B+ | [ ]  AB- | [ ]  AB+ |  |
|  |  |  | \_\_ \_\_ \_\_ |  | [ ]  O- | [ ]  O+ | [ ]  N/A |  |
| \_\_\_\_/\_\_\_\_/\_\_\_\_\_\_ | [ ]  ISBT-128 |  | \_\_ \_\_ \_\_ \_\_ \_\_ | \_\_\_/\_\_\_/\_\_\_\_\_\_ | [ ]  A- | [ ]  A+ | [ ]  B- | N |
|  | [ ]  Codabar |  | \_\_ \_\_ |  |  |  |  |  |
| \_\_\_ \_\_\_:\_\_\_ \_\_\_ | \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ |  | \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ | \_\_\_ \_\_\_:\_\_\_ \_\_\_ | [ ] B+ | [ ]  AB- | [ ]  AB+ |  |
|  |  |  | \_\_ \_\_ \_\_ |  | [ ]  O- | [ ]  O+ | [ ]  N/A |  |
| \_\_\_\_/\_\_\_\_/\_\_\_\_\_\_ | [ ]  ISBT-128 |  | \_\_ \_\_ \_\_ \_\_ \_\_ | \_\_\_/\_\_\_/\_\_\_\_\_\_ | [ ]  A- | [ ]  A+ | [ ]  B- | N |
|  | [ ]  Codabar |  | \_\_ \_\_ |  |  |  |  |  |
| \_\_\_ \_\_\_:\_\_\_ \_\_\_ | \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ |  | \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ | \_\_\_ \_\_\_:\_\_\_ \_\_\_ | [ ] B+ | [ ]  AB- | [ ]  AB+ |  |
|  |  |  | \_\_ \_\_ \_\_ |  | [ ]  O- | [ ]  O+ | [ ]  N/A |  |
| **Custom Fields** |
| Label |  | Label |  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_ \_\_/\_\_ \_\_/\_\_ \_\_ \_\_ \_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_ \_\_/\_\_ \_\_/\_\_ \_\_ \_\_ \_\_ |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Comments** |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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| **Component Details (continued)** |
| \*Transfusion **End** Date/Time  | \*Component code (check system used) | \*# of units | ^Unit number *Required for TRALI, GVHD, Infection* | \*Unit expiration Date/Time  | \*Blood group of unit | Implicated in the adverse reaction? |
| \_\_\_\_/\_\_\_\_/\_\_\_\_\_\_ | [ ]  ISBT-128 |  | \_\_ \_\_ \_\_ \_\_ \_\_ | \_\_\_/\_\_\_/\_\_\_\_\_\_ | [ ]  A- | [ ]  A+ | [ ]  B- | N |
|  | [ ]  Codabar |  | \_\_ \_\_ |  |  |  |  |  |
| \_\_\_ \_\_\_:\_\_\_ \_\_\_ | \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ |  | \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ | \_\_\_ \_\_\_:\_\_\_ \_\_\_ | [ ] B+ | [ ]  AB- | [ ]  AB+ |  |
|  |  |  | \_\_ \_\_ \_\_ |  | [ ]  O- | [ ]  O+ | [ ]  N/A |  |
| \_\_\_\_/\_\_\_\_/\_\_\_\_\_\_ | [ ]  ISBT-128 |  | \_\_ \_\_ \_\_ \_\_ \_\_ | \_\_\_/\_\_\_/\_\_\_\_\_\_ | [ ]  A- | [ ]  A+ | [ ]  B- | N |
|  | [ ]  Codabar |  | \_\_ \_\_ |  |  |  |  |  |
| \_\_\_ \_\_\_:\_\_\_ \_\_\_ | \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ |  | \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ | \_\_\_ \_\_\_:\_\_\_ \_\_\_ | [ ] B+ | [ ]  AB- | [ ]  AB+ |  |
|  |  |  | \_\_ \_\_ \_\_ |  | [ ]  O- | [ ]  O+ | [ ]  N/A |  |
| \_\_\_\_/\_\_\_\_/\_\_\_\_\_\_ | [ ]  ISBT-128 |  | \_\_ \_\_ \_\_ \_\_ \_\_ | \_\_\_/\_\_\_/\_\_\_\_\_\_ | [ ]  A- | [ ]  A+ | [ ]  B- | N |
|  | [ ]  Codabar |  | \_\_ \_\_ |  |  |  |  |  |
| \_\_\_ \_\_\_:\_\_\_ \_\_\_ | \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ |  | \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ | \_\_\_ \_\_\_:\_\_\_ \_\_\_ | [ ] B+ | [ ]  AB- | [ ]  AB+ |  |
|  |  |  | \_\_ \_\_ \_\_ |  | [ ]  O- | [ ]  O+ | [ ]  N/A |  |
| \_\_\_\_/\_\_\_\_/\_\_\_\_\_\_ | [ ]  ISBT-128 |  | \_\_ \_\_ \_\_ \_\_ \_\_ | \_\_\_/\_\_\_/\_\_\_\_\_\_ | [ ]  A- | [ ]  A+ | [ ]  B- | N |
|  | [ ]  Codabar |  | \_\_ \_\_ |  |  |  |  |  |
| \_\_\_ \_\_\_:\_\_\_ \_\_\_ | \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ |  | \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ | \_\_\_ \_\_\_:\_\_\_ \_\_\_ | [ ] B+ | [ ]  AB- | [ ]  AB+ |  |
|  |  |  | \_\_ \_\_ \_\_ |  | [ ]  O- | [ ]  O+ | [ ]  N/A |  |
| \_\_\_\_/\_\_\_\_/\_\_\_\_\_\_ | [ ]  ISBT-128 |  | \_\_ \_\_ \_\_ \_\_ \_\_ | \_\_\_/\_\_\_/\_\_\_\_\_\_ | [ ]  A- | [ ]  A+ | [ ]  B- | N |
|  | [ ]  Codabar |  | \_\_ \_\_ |  |  |  |  |  |
| \_\_\_ \_\_\_:\_\_\_ \_\_\_ | \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ |  | \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ | \_\_\_ \_\_\_:\_\_\_ \_\_\_ | [ ] B+ | [ ]  AB- | [ ]  AB+ |  |
|  |  |  | \_\_ \_\_ \_\_ |  | [ ]  O- | [ ]  O+ | [ ]  N/A |  |
| \_\_\_\_/\_\_\_\_/\_\_\_\_\_\_ | [ ]  ISBT-128 |  | \_\_ \_\_ \_\_ \_\_ \_\_ | \_\_\_/\_\_\_/\_\_\_\_\_\_ | [ ]  A- | [ ]  A+ | [ ]  B- | N |
|  | [ ]  Codabar |  | \_\_ \_\_ |  |  |  |  |  |
| \_\_\_ \_\_\_:\_\_\_ \_\_\_ | \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ |  | \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ | \_\_\_ \_\_\_:\_\_\_ \_\_\_ | [ ] B+ | [ ]  AB- | [ ]  AB+ |  |
|  |  |  | \_\_ \_\_ \_\_ |  | [ ]  O- | [ ]  O+ | [ ]  N/A |  |
| \_\_\_\_/\_\_\_\_/\_\_\_\_\_\_ | [ ]  ISBT-128 |  | \_\_ \_\_ \_\_ \_\_ \_\_ | \_\_\_/\_\_\_/\_\_\_\_\_\_ | [ ]  A- | [ ]  A+ | [ ]  B- | N |
|  | [ ]  Codabar |  | \_\_ \_\_ |  |  |  |  |  |
| \_\_\_ \_\_\_:\_\_\_ \_\_\_ | \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ |  | \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ | \_\_\_ \_\_\_:\_\_\_ \_\_\_ | [ ] B+ | [ ]  AB- | [ ]  AB+ |  |
|  |  |  | \_\_ \_\_ \_\_ |  | [ ]  O- | [ ]  O+ | [ ]  N/A |  |