

## Hemovigilance Module Adverse Reaction Infection

**\*Required for saving**

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |  |                                                                                                                                                               |  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|---------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| *Facility ID#: _____ NHSN Adverse Reaction #: _____                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |  |                                                                                                                                                               |  |
| <b>Patient Information</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |  |                                                                                                                                                               |  |
| *Patient ID: _____                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |  | *Date of Birth: ____/____/____                                                                                                                                |  |
| *Sex: <input type="checkbox"/> M <input type="checkbox"/> F                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  |                                                                                                                                                               |  |
| Social Security #: _____                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |  | Secondary ID: _____ Medicare #: _____                                                                                                                         |  |
| Last Name: _____                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |  | First Name: _____ Middle Name: _____                                                                                                                          |  |
| Ethnicity (Specify): <input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> Unknown <input type="checkbox"/> Declined to respond                                                                                                                                                                                                                                                                                                                                                                                                                                        |  |                                                                                                                                                               |  |
| Race (Select all that apply): <input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> Black or African American <input type="checkbox"/> Middle Eastern or North African <input type="checkbox"/> Native Hawaiian or Pacific Islander <input type="checkbox"/> White <input type="checkbox"/> Unknown <input type="checkbox"/> Declined to respond                                                                                                                                                                                                                          |  |                                                                                                                                                               |  |
| Preferred Language (Specify from the list provided): _____                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |  | Interpreter Needed: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown<br><input type="checkbox"/> Declined to Respond |  |
| *Blood Group: <input type="checkbox"/> A- <input type="checkbox"/> A+ <input type="checkbox"/> B- <input type="checkbox"/> B+ <input type="checkbox"/> AB- <input type="checkbox"/> AB+ <input type="checkbox"/> O- <input type="checkbox"/> O+ <input type="checkbox"/> Blood type not done<br><input type="checkbox"/> Transitional ABO / Rh + <input type="checkbox"/> Transitional ABO / Rh - <input type="checkbox"/> Rh<br><input type="checkbox"/> Group A/Transitional Rh <input type="checkbox"/> Group B/Transitional Rh <input type="checkbox"/> Group O/Transitional Rh <input type="checkbox"/> Group AB/Transitional Rh |  |                                                                                                                                                               |  |
| <b>Patient Medical History</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |  |                                                                                                                                                               |  |
| List the patient's admitting diagnosis. (Use ICD-10 Diagnostic codes/descriptions)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |  |                                                                                                                                                               |  |
| Code: _____                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  | Description: _____                                                                                                                                            |  |
| Code: _____                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  | Description: _____                                                                                                                                            |  |
| Code: _____                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  | Description: _____                                                                                                                                            |  |
| List the patient's underlying indication for transfusion. (Use ICD-10 Diagnostic codes/descriptions)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  |                                                                                                                                                               |  |
| Code: _____                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  | Description: _____                                                                                                                                            |  |
| Code: _____                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  | Description: _____                                                                                                                                            |  |
| Code: _____                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  | Description: _____                                                                                                                                            |  |
| List the patient's comorbid conditions at the time of the transfusion related to the adverse reaction. (Use ICD-10 Diagnostic codes/descriptions)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                                                                                                                                                               |  |
| Code: _____                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  | Description: _____                                                                                                                                            |  |
| Code: _____                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  | Description: _____                                                                                                                                            |  |
| Code: _____                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  | Description: _____                                                                                                                                            |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |  | <input type="checkbox"/> UNKNOWN<br><input type="checkbox"/> NONE                                                                                             |  |

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)). CDC 57.313 Rev. 3, v9.2

Public reporting burden of this collection of information is estimated to average 20 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 H21-8, Atlanta, GA 30333, ATTN: PRA (0920-0666).

List the patient's relevant medical procedure including past procedures and procedures to be performed during the current hospital or outpatient stay. (Use ICD-10 Procedure codes/descriptions) ☐ UNKNOWN ☐ NONE

Code: \_\_\_\_\_ Description: \_\_\_\_\_

Code: \_\_\_\_\_ Description: \_\_\_\_\_

Code: \_\_\_\_\_ Description: \_\_\_\_\_

Additional Information \_\_\_\_\_

### Transfusion History

Has the patient received a previous transfusion? ☐ YES ☐ NO ☐ UNKNOWN

Blood Product: ☐ WB ☐ RBC ☐ Platelet ☐ Plasma ☐ Cryoprecipitate ☐ Granulocyte

Date of Transfusion: \_\_\_\_/\_\_\_\_/\_\_\_\_ ☐ UNKNOWN

Was the patient's adverse reaction transfusion-related? ☐ YES ☐ NO

If yes, provide information about the transfusion adverse reaction.

Type of transfusion adverse reaction: ☐ Allergic ☐ AHTR ☐ DHTR ☐ DSTR ☐ FNHTR

☐ HTR ☐ TTI ☐ PTP ☐ TACO ☐ TAD ☐ TA-GVHD ☐ TRALI ☐ UNKNOWN

☐ OTHER Specify \_\_\_\_\_

### Reaction Details

\*Date reaction occurred: \_\_\_\_/\_\_\_\_/\_\_\_\_ \*Time reaction occurred: \_\_\_\_:\_\_\_\_ ☐ Time unknown

\*Facility location where patient was transfused: \_\_\_\_\_

Is this reaction associated with an incident? ☐ Yes ☐ No If Yes, Incident #: \_\_\_\_\_

### Investigation Results

\*☐ Infection

#### \*Case Definition

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 \_\_\_\_\_

Check all that apply:

☐ Temporally associated unexplained clinical illness consistent with infection

Other signs and symptoms: (check all that apply)

**Generalized:** ☐ Chills/rigors ☐ Fever ☐ Nausea/vomiting

|                                                 |                                                                 |                                              |
|-------------------------------------------------|-----------------------------------------------------------------|----------------------------------------------|
| <b>Cardiovascular:</b>                          | <input type="checkbox"/> Blood pressure decrease                | <input type="checkbox"/> Shock               |
| <b>Cutaneous:</b>                               | <input type="checkbox"/> Edema                                  | <input type="checkbox"/> Flushing            |
|                                                 | <input type="checkbox"/> Other rash                             | <input type="checkbox"/> Pruritus (itching)  |
| <b>Hemolysis/Hemorrhage:</b>                    | <input type="checkbox"/> Disseminated intravascular coagulation | <input type="checkbox"/> Hemoglobinemia      |
|                                                 | <input type="checkbox"/> Positive antibody screen               |                                              |
| <b>Pain:</b>                                    | <input type="checkbox"/> Abdominal pain                         | <input type="checkbox"/> Back pain           |
|                                                 | <input type="checkbox"/> Flank pain                             | <input type="checkbox"/> Infusion site pain  |
| <b>Renal:</b>                                   | <input type="checkbox"/> Hematuria                              | <input type="checkbox"/> Hemoglobinuria      |
|                                                 | <input type="checkbox"/> Oliguria                               |                                              |
| <b>Respiratory:</b>                             | <input type="checkbox"/> Bilateral infiltrates on chest x-ray   | <input type="checkbox"/> Bronchospasm        |
|                                                 | <input type="checkbox"/> Hypoxemia                              | <input type="checkbox"/> Shortness of breath |
| <input type="checkbox"/> Other: (specify) _____ |                                                                 |                                              |

### \*Severity

Did the patient receive or experience any of the following?

- |                                                                               |                                                                             |
|-------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| <input type="checkbox"/> No treatment required                                | <input type="checkbox"/> Symptomatic treatment only                         |
| <input type="checkbox"/> Hospitalization, including prolonged hospitalization | <input type="checkbox"/> Life-threatening reaction                          |
| <input type="checkbox"/> Disability and/or incapacitation                     | <input type="checkbox"/> Congenital anomaly or birth defect(s) of the fetus |
| <input type="checkbox"/> Other medically important conditions                 | <input type="checkbox"/> Death                                              |
|                                                                               | <input type="checkbox"/> Unknown or not stated                              |

### \*Imputability

Which best describes the relationship between the transfusion and the reaction?

- ☐ No other potential exposures to the pathogen could be identified in the recipient.
- ☐ Evidence is clearly in favor of a cause other than transfusion, but transfusion cannot be excluded.
- ☐ There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion.
- ☐ The relationship between the adverse reaction and the transfusion is unknown or not stated.

Check all that apply:

- ☐ Evidence of the pathogen in the transfused component.
- ☐ Evidence of the pathogen in the donor at the time of donation.
- ☐ Evidence of the pathogen in an additional component from the same donation.
- ☐ Evidence of the pathogen in an additional recipient of a component from the same donation.
- ☐ Evidence that the identified pathogen strains are related by molecular or extended phenotypic comparison testing with statistical confidence ( $p < 0.05$ ).
- ☐ Evidence that the transfused component was negative for this pathogen at the time of transfusion
- ☐ Evidence that the donor was negative for this pathogen at the time of donation.
- ☐ Evidence that additional components from the same donation were negative for this pathogen.
- ☐ Evidence that the recipient was not infected with the pathogen prior to transfusion.
- ☐ Laboratory evidence that the recipient was infected with this pathogen prior to transfusion.

Did the transfusion occur at your facility? ☐ YES ☐ NO

### Module-generated Designations

*NOTE: Designations for case definition, severity, and imputability will be automatically assigned in the NHSN application based on responses in the corresponding investigation results section above.*

**\*Do you agree with the case definition designation?**

☐ YES ☐ NO

^Please indicate your designation \_\_\_\_\_

**\*Do you agree with the severity designation?**

☐ YES

☐ NO

^Please indicate your designation \_\_\_\_\_

**\*Do you agree with the imputability designation?**

☐ YES

☐ NO

^Please indicate your designation \_\_\_\_\_

## Patient Treatment

Did the patient receive treatment for the transfusion reaction?

☐ YES

☐ NO

☐ UNKNOWN

If yes, select treatment(s):

☐ Medication (*Select the type of medication*)

☐ Antipyretics   ☐ Antihistamines   ☐ Inotropes/Vasopressors   ☐ Bronchodilator   ☐ Diuretics

☐ Intravenous

Immunoglobulin

☐ Intravenous steroids

☐ Corticosteroids

☐ Antibiotics

☐ Antithymocyte globulin

☐ Cyclosporin

☐ Other

☐ Volume resuscitation (Intravenous colloids or crystalloids)

☐ Respiratory support (*Select the type of support*)

☐ Mechanical ventilation

☐ Noninvasive ventilation

☐ Oxygen

☐ Renal replacement therapy (*Select the type of therapy*)

☐ Hemodialysis

☐ Peritoneal

☐ Continuous Veno-Venous Hemofiltration

☐ Phlebotomy

☐ Other Specify: \_\_\_\_\_

## Outcome

**\*Outcome:** ☐ Death   ☐ Major or long-term sequelae   ☐ Minor or no sequelae   ☐ Not determined

Date of Death: \_\_\_\_/\_\_\_\_/\_\_\_\_

^If recipient died, relationship of transfusion to death:

☐ Definite

☐ Probable

☐ Possible

☐ Doubtful

☐ Ruled Out

☐ Not determined

Cause of death: \_\_\_\_\_

Was an autopsy performed? ☐ Yes   ☐ No

## Component Details

**\*Was a particular unit implicated in (i.e., responsible for) the adverse reaction?**

☐ Yes

☐ No

☐ N/A

| Transfusion Start and End Date/Time | *Component code (check system used)                                   | Amount transfused at reaction onset                                                    | ^Unit number (Required for Infection and TRALI) | *Unit expiration Date/Time       | *Blood group of unit                                                                                                                                                                                                                                                 | Implicated Unit? |
|-------------------------------------|-----------------------------------------------------------------------|----------------------------------------------------------------------------------------|-------------------------------------------------|----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|
| ____/____/____<br>____:____:____    | <input type="checkbox"/> ISBT-128<br><input type="checkbox"/> Codabar | <input type="checkbox"/> Entire unit<br><input type="checkbox"/> Partial unit _____ mL | ____-____-____<br>____-____-____                | ____/____/____<br>____:____:____ | <input type="checkbox"/> A- <input type="checkbox"/> A+ <input type="checkbox"/> B-<br><input type="checkbox"/> B+ <input type="checkbox"/> AB- <input type="checkbox"/> AB+<br><input type="checkbox"/> O- <input type="checkbox"/> O+ <input type="checkbox"/> N/A | Y                |
| ____/____/____<br>____:____:____    | <input type="checkbox"/> ISBT-128                                     | <input type="checkbox"/> Entire unit                                                   | ____-____-____<br>____-____-____                | ____/____/____<br>____:____:____ | <input type="checkbox"/> A- <input type="checkbox"/> A+ <input type="checkbox"/> B-                                                                                                                                                                                  | N                |

|                                          |                                              |                                                          |              |              |                                |              |              |              |
|------------------------------------------|----------------------------------------------|----------------------------------------------------------|--------------|--------------|--------------------------------|--------------|--------------|--------------|
| ____:____<br>____/____/____<br>____:____ | <input type="checkbox"/> Codabar<br><br>____ | <input type="checkbox"/> Partial unit<br>____ mL<br>____ | ____<br>____ | ____<br>____ | ____<br>____                   | ____<br>____ | ____<br>____ | ____<br>____ |
| <b>Custom Fields</b>                     |                                              |                                                          |              |              |                                |              |              |              |
| Label                                    |                                              |                                                          |              |              | Label                          |              |              |              |
| _____ / _____ / _____<br>_____           |                                              |                                                          |              |              | _____ / _____ / _____<br>_____ |              |              |              |
| <b>Comments</b>                          |                                              |                                                          |              |              |                                |              |              |              |
|                                          |                                              |                                                          |              |              |                                |              |              |              |