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OMB No. 0920-xxxx
Exp. Date: XX/XX/20XX
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Hemovigilance Module
Adverse Reaction
Infection

*Required for saving

*Facility ID#: _____ NHSN Adverse Reaction #: _____

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+ ☐ Blood type not done

Patient Medical History (Use worksheet on page 4 for additional codes and descriptions.)

(part 1) List the patient's admitting diagnosis. *(Use ICD-10 Diagnostic codes/descriptions)*

Code: _____ Description: _____
Code: _____ Description: _____
Code: _____ Description: _____

(part 2) List the patient's underlying indication for transfusion. *(Use ICD-10 Diagnostic codes/descriptions)*

Code: _____ Description: _____
Code: _____ Description: _____
Code: _____ Description: _____

(part 3) List the patient's comorbid conditions at the time of the transfusion related to the adverse reaction. *(Use ICD-10 Diagnostic codes/descriptions)*

☐ UNKNOWN
☐ NONE

Code: _____ Description: _____
Code: _____ Description: _____
Code: _____ Description: _____

Continued >>

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)).

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Infection

Patient Medical History (Use worksheet on page 4 for additional codes and descriptions.)

(part 4) 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: _____

(part 5) Additional Information _____

_____

_____

Transfusion History (Use worksheet on page 4 for additional transfusion history.)

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

***If yes, provide information about the transfusion event. If not, skip to Reaction Details section.*

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

Date of Transfusion: ___/___/____ ☐ UNKNOWN

Did the patient experience a transfusion adverse reaction? ☐ 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 #: _____

After recognition of the transfusion reaction, was the current transfusion:
☐ Continued ☐ Stopped and restarted ☐ Stopped indefinitely

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 _____

Continued >>

Infection

Investigation Results (continued)

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

☐ None of the above

Other signs and symptoms: (check all that apply)

Generalized:	☐ Chills/rigors ☐ Fever ☐ Nausea/vomiting
Cardiovascular:	☐ Blood pressure decrease ☐ Shock
Cutaneous:	☐ Edema ☐ Flushing ☐ Jaundice ☐ Other rash ☐ Pruritus (itching) ☐ Urticaria (hives)
Hemolysis/Hemorrhage:	☐ Disseminated intravascular coagulation ☐ Hemoglobinemia ☐ Positive antibody screen
Pain:	☐ Abdominal pain ☐ Back pain ☐ Flank pain ☐ Infusion site pain
Renal:	☐ Hematuria ☐ Hemoglobinuria ☐ Oliguria
Respiratory:	☐ Bilateral infiltrates on chest x-ray ☐ Bronchospasm ☐ Cough ☐ Hypoxemia ☐ Shortness of breath

☐ Other: (specify)

_____

Severity

Did the patient receive or experience any of the following? *(Response definitions listed in protocol)*

☐ Symptomatic treatment only ☐ Hospitalization, inlcuding prolonged hospitalization

☐ Life-threatening reaction ☐ Disability and/or incapacitation

☐ Congenital anomaly or birth defect(s) of the fetus ☐ Death

☐ Other medically important conditions ☐ 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.

Continued >>

Infection

Investigation Results (continued)

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

Additional Information _____

_____

_____

Patient Treatment

*Did the patient receive treatment for the transfusion reaction? ☐ YES ☐ NO

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 ☐ H1 receptor blockers ☐ 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: _____

Continued >>

Infection

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 (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 **Start** and **End** Date/Time	*Component code (check system used)	*Amount transfused at reaction onset	*Unit number	*Unit expiration Date/Time	*Blood group of unit	Implicated Unit?
^IMPLICATED UNIT						
____/____/___ ___ ___:_____ ____/____/___ ___ ___:_____	☐ ISBT-128 ☐ Codabar ___ ___ ___ ___ ___ _____	☐ Entire unit ☐ Partial unit _____mL	__ __ __ __ __ __ __ __ __ __ __ __ __ __ __	___/___/_____ _____:_____	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A	Y
____/____/___ ___ ___:___ _ ____/____/___ ___ ___:_____	☐ ISBT-128 ☐ Codabar ___ ___ ___ ___ ___ _____	☐ Entire unit ☐ Partial unit _____mL	__ __ __ __ __ __ __ __ __ __ __ __ __ __ __	___/___/_____ _____:_____	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A	N
____/____/___ ___ ___:_____ ____/____/___ ___ ___:___ __	☐ ISBT-128 ☐ Codabar ___ ___ ___ ___ ___ _____	☐ Entire unit ☐ Partial unit _____mL	__ __ __ __ __ __ __ __ __ __ __ __ __ __ __	___/___/_____ _____:_____	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A	N

Custom Fields

Label		Label	
_____	_____/_____/_____	_____	_____/_____/_____
_____	_____	_____	_____
_____	_____	_____	_____

Comments

_____

_____

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Hemovigilance Module
Additional Worksheet

Patient Medical History

(part 1) List the patient's admitting diagnosis. *(Use ICD-10 Diagnostic codes/descriptions)*

Code: _____ Description: _____
Code: _____ Description: _____
Code: _____ Description: _____
Code: _____ Description: _____
Code: _____ Description: _____
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(part 2) List the patient's underlying indication for transfusion. *(Use ICD-10 Diagnostic codes/descriptions)*

Code: _____ Description: _____
Code: _____ Description: _____
Code: _____ Description: _____
Code: _____ Description: _____
Code: _____ Description: _____
Code: _____ Description: _____

(part 3) List the patient's comorbid conditions at the time of the transfusion related to the adverse reaction. *(Use ICD-10 Diagnostic codes/descriptions)*

☐ UNKNOWN
☐ NONE

Code: _____ Description: _____
Code: _____ Description: _____
Code: _____ Description: _____
Code: _____ Description: _____
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Code: _____ Description: _____

(part 4) 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)*

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☐ NONE

Code: _____ Description: _____
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(part 5) Additional Information _____

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_____

_____

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Hemovigilance Module
Additional Worksheet

Transfusion History

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

***If yes, provide information about the transfusion event. If not, skip to Reaction Details section.*

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

Date of Transfusion: ____/____/_____ ☐ UNKNOWN

Did the patient experience a transfusion adverse reaction? ☐ 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 _____

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

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Additional Worksheet

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	*Unit expiration Date/Time	*Blood group of unit			Implicated Unit?
____/____/_____ ___ ___:___ ___ ____/____/_____ ___ ___:___ ___	☐ ISBT-128 ☐ Codabar ___ ___ ___ ___ ___ _____	☐ Entire unit ☐ Partial unit _____mL	__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	___/___/_____ _____ : _____	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A			N
____/____/_____ ___ ___:___ ___ ____/____/_____ ___ ___:___ ___	☐ ISBT-128 ☐ Codabar ___ ___ ___ ___ ___ _____	☐ Entire unit ☐ Partial unit _____mL	__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	___/___/_____ _____ : _____	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A			N
____/____/_____ ___ ___:___ ___ ____/____/_____ ___ ___:___ ___	☐ ISBT-128 ☐ Codabar ___ ___ ___ ___ ___ _____	☐ Entire unit ☐ Partial unit _____mL	__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	___/___/_____ _____ : _____	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A			N
____/____/_____ ___ ___:___ ___ ____/____/_____ ___ ___:___ ___	☐ ISBT-128 ☐ Codabar ___ ___ ___ ___ ___ _____	☐ Entire unit ☐ Partial unit _____mL	__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	___/___/_____ _____ : _____	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A			N
____/____/_____ ___ ___:___ ___ ____/____/_____ ___ ___:___ ___	☐ ISBT-128 ☐ Codabar ___ ___ ___ ___ ___ _____	☐ Entire unit ☐ Partial unit _____mL	__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	___/___/_____ _____ : _____	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A			N
____/____/_____ ___ ___:___ ___ ____/____/_____ ___ ___:___ ___	☐ ISBT-128 ☐ Codabar ___ ___ ___ ___ ___ _____	☐ Entire unit ☐ Partial unit _____mL	__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	___/___/_____ _____ : _____	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A			N
____/____/_____	☐ ISBT-128	☐ Entire	__ __ __ __ __	___/___/_____	☐	☐ A+	☐ B-	N

___ ___:___ ___ ____/____/_____ ___ ___:___ ___	☐ Codabar ___ ___ ___ ___ ___ _____	unit ☐ Partial unit _____mL	__ __ __ __ __ __ __ __ __ __ __ _____	_____ _____ : _____	A- ☐ B + ☐ O-	☐ AB- ☐ O+	☐ AB+ ☐ N/A	