OMB No. 0920-0666
Exp. Date: XX-XX-XXXX

Hemovigilance Module
Adverse Reaction

*Required for saving

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

Patient Information

*Patient ID: _____ Social Security #: _____ Secondary ID: _____

Last Name: _____ First Name: _____ Middle Name: _____

*Gender: ☐ M ☐ F ☐ Other *Date of Birth: __ __/__ __/__ __ __ __

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 reaction occurred: _____

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

*Signs and symptoms, laboratory: (check all that apply)

Cardiovascular:
- ☐ Blood pressure decrease
- ☐ Shock

Hemolysis/Hemorrhage
- ☐ Disseminated intravascular coagulation
- ☐ Hemoglobinemia
- ☐ Positive antibody screen

Generalized:
- ☐ Chills/rigors
- ☐ Fever

Cutaneous:
- ☐ Edema
- ☐ Flushing
- ☐ Jaundice
- ☐ Other rash
- ☐ Pruritis
- ☐ Urticaria

Renal:
- ☐ Hematuria
- ☐ Hemoglobinuria
- ☐ Oliguria

Pain:
- ☐ Abdominal pain
- ☐ Back pain
- ☐ Flank pain
- ☐ Infusion site pain

Respiratory:
- ☐ Bilateral infiltrates on chest x-ray
- ☐ Bronchospasm
- ☐ Cough
- ☐ Hypoxemia
- ☐ 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)).

Component Details (Use worksheet on page 4 for additional units.)

*Transfusion Date/Time MM/DD/YYYY HH:MM	*Component code (check system used)	*# of units	^Unit number *Required for TRALI, GVHD, Infection*	*Expiration Date/Time MM/DD/YYYY HH:MM	*Blood group of unit	Implicated in the adverse reaction?
___/___/_____ __ __:__ __	☐ ISBT-128 ☐ Codabar __ __ __ __ __		__ __ __ __ __ __ __ __ __ __ __ __ __ __ __	___/___/_____ __ __:__ __	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A	☐
___/___/_____ __ __:__ __	__ __ __ __ __		__ __ __ __ __ __ __ __ __ __ __ __ __ __ __	___/___/_____ __ __:__ __	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A	☐
___/___/_____ __ __:__ __	__ __ __ __ __		__ __ __ __ __ __ __ __ __ __ __ __ __ __ __	___/___/_____ __ __:__ __	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A	☐

Investigation Results (Use case definition criteria in protocol.)

*Was a particular unit implicated in the adverse reaction? ☐ Yes ☐ No

*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: _____

☐ Febrile non-hemolytic transfusion reaction (FNHTR)

☐ Hypotensive transfusion reaction

☐ Infection

Was a test to detect a specific pathogen performed on the recipient 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 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 pathophysiology

☐ 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

Custom Fields

Label		Label	
_____	__ __/__ __/__ __ __ __	_____	__ __/__ __/__ __ __ __
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Comments

_____

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Component Details

*Transfusion Date/Time MM/DD/YYYY HH:MM	*Component code (check system used)	*# of units	^Unit number *Required for TRALI, GVHD, Infection*	*Expiration Date/Time MM/DD/YYYY HH:MM	*Blood group of unit	Implicated in the adverse reaction?
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___/___/______ __ __:__ __	__ __ __ __ __		__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	___/___/______ __ __:__ __	☐ A- ☐ A+ ☐ B- ☐ B+ ☐ AB- ☐ AB+ ☐ O- ☐ O+ ☐ N/A	☐