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

Hemovigilance Adverse Reaction

* Required Field

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

Patient Information

*Patient ID: _____ *Gender: ☐ M ☐ F *Date of birth: ___/__/_____

*Patient's blood group: ☐ A+ ☐ A- ☐ B+ ☐ B- ☐ O+ ☐ O- ☐ AB+ ☐ AB-

Reaction Details

*Date reaction occurred: ___/___/_____

*Time reaction occurred: __ __: __ __ (HH:MM)
OR Time unknown ☐

*Facility location where reaction occurred:
_____

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

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

☐ Chills/rigors ☐ Fever ☐ Urticaria ☐ Other skin rash ☐ Shortness of breath ☐ Hypoxemia
☐ Decrease in blood pressure ☐ Increase in blood pressure ☐ Diffuse hemorrhage ☐ Shock ☐ Jaundice
☐ Nausea/vomiting ☐ Dark urine ☐ Oliguria ☐ Hematuria ☐ Hemoglobinemia
☐ Abdominal pain ☐ Back pain ☐ Chest pain ☐ Flank pain ☐ Headache ☐ Pain at infusion site
☐ Other pain (specify) _____ ☐ Other (specify) _____

Component Details (Use worksheet on page 3 for additional units)

*Date / Time MM/DD/YYYY HH:MM	*Component code (Check system used) ☐ ISBT-128 ☐ Codabar	*# of Units	Unit number *Required for TRALI, GVHD, Infection	*Unit expiration date MM/DD/YYYY	*Blood group of unit	Implicated in the adverse reaction?
__/__/____ __ __:__ __	__ __ __ __ __		__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	__/__/____	☐A+ ☐B+ ☐O+ ☐AB+ ☐A- ☐B- ☐O- ☐AB- ☐N/A	☐
__/__/____ __ __:__ __	__ __ __ __ __		__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	__/__/____	☐A+ ☐B+ ☐O+ ☐AB+ ☐A- ☐B- ☐O- ☐AB- ☐N/A	☐

Investigation Results (See Case Definition Criteria)

*Was a particular unit implicated in the adverse reaction? ☐ YES ☐ NO

Assurance of Confidentiality: The 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 57.304

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*Adverse reaction (Select one):

☐ Allergic reaction, including anaphylaxis

Hemolytic transfusion reaction:

☐ 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

☐ Hypotensive transfusion reaction

☐ Infection A. ☐ Bacterial (incl. sepsis) ☐ Viral ☐ Other B. Organism (specify)_____

Blood culture performed on unit: ☐ YES ☐ NO

If YES, were any culture results positive ☐ YES Organism_____ ☐ NO

Blood culture performed on recipient post-transfusion: ☐ YES ☐ NO

If YES, were any culture results positive ☐ YES Organism_____ ☐ NO

☐ Post transfusion purpura (PTP)

☐ Transfusion associated circulatory overload (TACO)

☐ Transfusion associated dyspnea (TAD)

☐ Transfusion associated graft vs. host disease (TA-GVHD)

Has the patient received any non-irradiated blood product(s) in the past two months? ☐ Yes ☐ No

☐ Transfusion related acute lung injury (TRALI)

(*Optional*) Antibody studies performed:

	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) _____

i. Meets Case Definition Criteria: *Def = Definitive, Pro = Probable, Pos= Possible, NA*
ii. Grade: *NS= Non-severe, S = Severe, LT = Life-threatening, D = Death, ND= Not Determined*
iii. Relationship to Transfusion*: Def =Definite, Pro =Probable, Pos =Possible, Dou=Doubtful, RO= Ruled out, ND*

*For adverse reaction selected indicate: i. Case Definition Criteria ____ ii. Grade ____ iii. Relationship ____

Outcome

*☐ Death+ ☐ Major or long-term sequelae ☐ Minor or no sequelae ☐ Not determined

Date of death ____/____/_____

+Note: 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:

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Hemovigilance Adverse Reaction

Label			
_____	___/___/___	_____	___/___/____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Comments:

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Worksheet for Additional Units

Component Details						
*Date / Time MM/DD/YYYY HH:MM	*Component code (Check system used) ☐ ISBT-128 ☐ Codabar	*# of Units	Unit number * Required for TRALI, GVHD, Infection	*Unit expiration date MM/DD/YYYY	*Blood group of unit	Implicated in the Adverse Reaction?
__/__/____ __ __:__ __	__ __ __ __ __		__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	__/__/____	☐A+ ☐B+ ☐O+ ☐AB+ ☐A- ☐B- ☐O- ☐AB- ☐N/A	☐
__/__/____ __ __:__ __	__ __ __ __ __		__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	__/__/____	☐A+ ☐B+ ☐O+ ☐AB+ ☐A- ☐B- ☐O- ☐AB- ☐N/A	☐
__/__/____ __ __:__ __	__ __ __ __ __		__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	__/__/____	☐A+ ☐B+ ☐O+ ☐AB+ ☐A- ☐B- ☐O- ☐AB- ☐N/A	☐
__/__/____ __ __:__ __	__ __ __ __ __		__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	__/__/____	☐A+ ☐B+ ☐O+ ☐AB+ ☐A- ☐B- ☐O- ☐AB- ☐N/A	☐
__/__/____ __ __:__ __	__ __ __ __ __		__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	__/__/____	☐A+ ☐B+ ☐O+ ☐AB+ ☐A- ☐B- ☐O- ☐AB- ☐N/A	☐
__/__/____ __ __:__ __	__ __ __ __ __		__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	__/__/____	☐A+ ☐B+ ☐O+ ☐AB+ ☐A- ☐B- ☐O- ☐AB- ☐N/A	☐
__/__/____ __ __:__ __	__ __ __ __ __		__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	__/__/____	☐A+ ☐B+ ☐O+ ☐AB+ ☐A- ☐B- ☐O- ☐AB- ☐N/A	☐
__/__/____ __ __:__ __	__ __ __ __ __		__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	__/__/____	☐A+ ☐B+ ☐O+ ☐AB+ ☐A- ☐B- ☐O- ☐AB- ☐N/A	☐
__/__/____ __ __:__ __	__ __ __ __ __		__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	__/__/____	☐A+ ☐B+ ☐O+ ☐AB+ ☐A- ☐B- ☐O- ☐AB- ☐N/A	☐
__/__/____ __ __:__ __	__ __ __ __ __		__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	__/__/____	☐A+ ☐B+ ☐O+ ☐AB+ ☐A- ☐B- ☐O- ☐AB- ☐N/A	☐