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OMB No. 0920-0666
Exp. Date: xx/xx/20xx
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Hemovigilance Module
Adverse Reaction
Post Transfusion Purpura

*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 >>

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Post Transfusion Purpura

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

*☐ **Post transfusion purpura (PTP)**

*Case Definition

Check all that occurred after cessation of transfusion :

☐ Alloantibodies in the patient directed against HPA or other platelet specific antigen detected at or after development of thrombocytopenia.

☐ Thrombocytopenia (i.e., decrease in platelets to less than 20% of pre-transfusion count).

☐ Decrease in platelets to levels between 20% and 80% of pre-transfusion count.

Continued >>

Post Transfusion Purpura

Investigation Results (continued)

Indicate the case definition (check all that apply):

- ☐ PTP is suspected, but laboratory findings and/or information are not sufficient. NOTE: For example, the patient has a drop in platelet count to less than 80% of pre-transfusion count but HPA antibodies were not tested or were negative.
- ☐ 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?

- ☐ Patient has no other conditions to explain thrombocytopenia.
- ☐ There are other potential causes present that could explain thrombocytopenia, but transfusion is the most likely cause.
- ☐ Alternate explanations for thrombocytopenia are more likely, but transfusion cannot be ruled out.
- ☐ Evidence is clearly in favor of a cause other than the 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.

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

When did the reaction occur in relation to the transfusion?

- ☐ Occurred 5-12 days post-transfusion

☐ Occurred less than 5 or more than 12 days post-transfusion

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Post Transfusion Purpura

Investigation Results (continued)

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 _____		

Additional Information _____

_____

_____

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 ☐ 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: _____

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

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Post Transfusion Purpura

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: _____
Code: _____ Description: _____

(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: _____
Code: _____ Description: _____
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)*

☐ UNKNOWN
☐ NONE

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

(part 5) Additional Information _____
_____
_____
_____

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 ____________________

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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	