NEW YORK STATE DEPARTMENT OF HEALTH
WADSWORTH CENTER
Clinical Laboratory Evaluation Program – Blood Resources

Intake #_____
(DOH Use only)

Transfusion/Blood Bank-related Incident and/or Serious Adverse Reaction Report

Facility name/city _____ **Lab PFI#** _____

Instructions for reporting

Transfusion/Blood Bank-related incidents and/or serious adverse reactions must be reported to the department's Wadsworth Center within seven calendar days of the occurrence or its discovery.

Events that must be reported include, but are not limited to:

- Serious (severe) unexpected adverse reactions and incidents involving blood components that have been issued by the transfusion service
- All incidents, including near miss events, resulting in transfusion of a blood or blood component to a wrong patient
- Patient bedside identification not performed or performed incorrectly
- Issuance of incorrect product or unit for a specific patient
- Specimen labeling errors if a patient specimen used for a crossmatch was collected from the wrong patient or labeled with erroneous patient identifiers, and the blood component was issued for transfusion
- Pre-transfusion testing errors of the recipient blood, if a patient sample was used in crossmatching blood or blood component that has been issued for transfusion
- Errors or accidents in collecting, testing, or processing of donor blood that are not detected prior to distribution and that may affect the safety of any product or health of the donor or recipient, including serious donor reactions

The decision to report should be based on whether the event had the potential to affect the safety or purity of any product, or the health of donor or recipient.

Definitions

Incidents related to transfusion include **errors** and **accidents** which may affect the safety, purity or potency of blood product, or health of the donor or recipient. An incident may or may not result in an adverse reaction in a transfusion recipient.

An **error** is a deviation from the requirements specified in Subpart 58-2 of Title 10 of the New York State Codes, Rules and Regulations (10 NYCRR), or the Code of Federal Regulations (CFR), or a significant deviation from the facility's Standard Operating Procedures (SOPs).

An **accident** related to transfusion is an unexpected or unforeseeable event not traceable to a deviation from Subpart 58-2 of 10 NYCRR, CFR or the facility's SOPs

Serious (severe) adverse reaction related to transfusion is reportable if the reaction is fatal or life threatening, results in hospitalization (initial or prolonged), disability/permanent damage, or required intervention to prevent permanent impairment.

What not to report:

- Non-severe adverse reactions to transfusion
- Errors and accidents that were detected prior to distribution and/or issuance of blood or blood components for transfusion
- Errors and accidents that did not have potential to affect the safety or purity of blood or blood component or health of donor or recipient
- Labeling deviation that does not result in erroneous patient identification. A deviation from protocol is a nonconformance that must be investigated by the blood bank, but is not reportable unless there is risk of erroneous patient identifiers
- Post-donation information
- Post-donation reactions that occured more than 30 minutes or after the donor has left the premises of the donation location.
- Positive bacteria detection testing on platelets, absent a process error or severe transfusion reaction
- Nursing/Medical staff errors related to monitoring patients during transfusion, or reporting transfusion reactions, **absent adverse patient effect**
- "Lookbacks" performed by the facility, **absent infectious disease transmission in a transfusion recipient**

Facility name/city _____ **Lab PFI#**_____

Date of discovery **Facility incident number**_____

Date of occurrence **Time of occurrence** _____ ☐ **AM** ☐ **PM**

Date of report

Person filing report _____ **Title**_____

Telephone number_____ **Email address**_____

◯ **INCIDENT REPORT** ◯ **ADVERSE REACTION REPORT**

Patient effect(s)

☐ Not applicable
☐ No effect apparent
☐ Fatality – likely related to transfusion
☐ Fatality – possibly related to transfusion, cause to be determined
☐ Acute hemolytic transfusion reaction (AHTR)
☐ Delayed hemolytic transfusion reaction (DHTR) ☐
☐ Graft-vs-host disease (GVHD)
☐ Transfusion-related acute lung injury (TRALI)
☐ Transfusion-associated circulatory overload (TACO)
☐ Transfusion-associated infectious disease (specify)
☐ Posttransfusion purpura
☐ Sepsis
☐ Other (specify)
  - ☐ Allergic reaction, severe
  - ☐ Transfusion-associated dyspnea
  - ☐ Hypotensive transfusion reaction
  - ☐ Febrile non-hemolytic transfusion reaction

Donor effect(s)

☐ Not applicable
☐ No effect apparent
☐ Significant donor reaction (specify) _____
☐ Other (specify) _____

At what point(s) in the process did the incident occur?

- ☐ Not applicable
- ☐ Donor history
- ☐ Blood collection/donor testing
- ☐ Component preparation
- ☐ Product labeling
- ☐ Product check-in
- ☐ Product manipulation
- ☐ Product storage
- ☐ Sample collection/labeling
- ☐ Product order
- ☐ Patient sample testing
- ☐ Clerical/documentation
- ☐ Product selection
- ☐ Request for pick-up
- ☐ Product labeling for issue
- ☐ Product issuance
- ☐ Product administation
- ☐ Equipment function
- ☐ Special attribute(s)
- ☐ Other (specify) _____

How was the incident discovered? (check one)

- ☐ Bedside patient identification
- ☐ Transfusion reaction
- ☐ Supervisory review
- ☐ Subsequent blood request
- ☐ Subsequent blood donation
- ☐ Audit
- ☐ Computer warning
- ☐ Historical record check
- ☐ Discrepant lab results
- ☐ Review of order
- ☐ Reported by consignee
- ☐ Other (specify) _____

Where did the incident occur? (check all that apply)

- ☐ Blood center
- ☐ Blood bank/lab
- ☐ ED
- ☐ ICU
- ☐ OR
- ☐ OB
- ☐ Med/Surg/Peds
- ☐ Outpatient Tx
- ☐ Limited Tx Service
- ☐ Limited Reinfusion Service
- ☐ Other (specify) _____

Job function of the worker(s) involved in the incident (check all that apply)

- ☐ Clinical Laboratory Technologist
- ☐ Clerical/Administrative
- ☐ RN, LPN, NP, PA
- ☐ Attending Physician
- ☐ Phlebotomist/IV Team
- ☐ Housestaff
- ☐ Other (specify) _____

Product involved (check all that apply)

- ☐ Not applicable
- ☐ RBCs
- ☐ Platelets
- ☐ FFP/24-hour plasma
- ☐ Cryoprecipitate
- ☐ Plasma derivative
- ☐ Reinfusion product
- ☐ Other
- ☐ Allogeneic/community donation
- ☐ Autogeneic donation
- ☐ Directed donation
- ☐ Perioperative blood recovery
- ☐ Prepared from whole blood
- ☐ Collected by apheresis

Quantity administered

- ☐ None
- ☐ ≤25 mL
- ☐ 26-50 mL
- ☐ 51-100 mL
- ☐ 101-200 mL
- ☐ Entire unit/product
- ☐ # of units_____

_____

Patient		Unit		Compatibility
☐ O pos	☐ O neg	☐ O pos	☐ O neg	☐ Compatible
☐ A pos	☐ A neg	☐ A pos	☐ A neg	☐ Incompatible
☐ B pos	☐ B neg	☐ B pos	☐ B neg	☐ N/A
☐ AB pos	☐ AB neg	☐ AB pos	☐ AB neg	
☐ N/A		☐ N/A		

Was there a reaction? ☐ Yes ☐ No ☐ N/A

Was a transfusion reaction workup performed? ☐ Yes ☐ No ☐ N/A

Incident summary (attach a separate page if necessary)

Results of investigation: investigate to determine what, who, how, why and when the event occurred. (attach a separate page if necessary)

Was a root cause analysis performed? ☐ Yes ☐ No

Please refer to the Plan of Correction (POC) Guidance Document at https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/on-site-survey for information on performing a Root Cause Analysis.

Corrective action (attach a separate page if necessary):

Please scan the completed form and send as an e-mail attachment to brp@health.ny.gov with a subject title of Incident Report and your facility's PFI number. Alternatively, it can be mailed to the Blood Resources Program at the address below. Questions should be directed to the Blood and Resources Program at brp@health.ny.gov.

CLEP – Blood Resources
Wadsworth Center
NYS Department of Health
Empire State Plaza
Albany, NY 12237