Hemovigilance Module
Adverse Reaction
Investigation Form

Data Field	Instructions for Form Completion
Facility ID#	**Required.** The NHSN- assigned Facility ID number will be auto generated by the NHSN application.
Reporter Name	**Required.** Select the name of the facility's personnel that will be completing and submitting the form.
NHSN Adverse Reaction #	An adverse reaction number will be auto generated by the NHSN application.
Recipient Information	
Last Name	Optional. List the recipient's last name.
First Name	Optional. List the recipient's first name.
Middle Name	Optional. List the recipient's middle name.
Patient ID	**Required.** Enter the medical record number or other facility alphanumeric identification code for the patient. *Note: Facility patient information is shared across NHSN Component. When an MRN is entered for a patient that has been previously entered for another NHSN event, the patient information will automatically populate. NHSN is HIPPA compliant; it is not recommended to devise a unique patient identifier for NHSN.*
Date of Birth	**Required.** Enter the date of the birth of the transfusion recipient.
State of Residence	**Required.** Select the state of residence for the transfusion recipient.
Sex	**Required.** Select the sex of the transfusion recipient.
Medical Record#	**Required.** List the facility's record number for the recipient.
Ethnicity	Optional. Select the transfusion recipient's ethnicity.
Race	Optional. Indicate the transfusion recipient's race. Select all that apply.
Blood group	Optional. Select the blood group of the transfusion recipient. *Note: If the recipient's blood type does not clearly match a single blood type, select the most relevant blood type and make a note in the comments section of the form. For example, if a recipient is typing with mixed field reactions following a bone marrow transplant, select the predominant blood type and enter a note in the comments section such as, "Group A recipient of group O bone marrow transplant currently typing as mixed field."*
Recipient Medical History	
Did the recipient have any of the following comorbid	**Required.** Indicate if the recipient had sickle cell disease or thalassemia at the time of the transfusion.

Data Field	Instructions for Form Completion
conditions present at the time of transfusion?	
Sickle cell disease	Select 'Yes', 'No', or 'Unknown'.
Thalassemia	Select 'Yes', 'No', or 'Unknown'.
Recipient Adverse Reaction Details	
Date reaction occurred (Onset Date)	**Required.** Enter the date the reaction was first observed in the transfusion recipient or mark 'Unknown'.
Time reaction occurred	Optional. Enter the time the reaction was first observed in the transfusion recipient using a 24-hour clock or mark 'Unknown'.
Did the transfusion occur at your facility?	**Required.** Indicate whether the recipient's transfusion occurred at your facility by selecting either 'Yes' or 'No'.
If no, facility name:	**Required.** Enter the facility's name where the transfusion occurred.
If no, facility address:	**Required.** Enter the facility's address where the transfusion occurred.
Facility location where patient was transfused	Optional. Based on CDC location list, select the facility location where the patient was transfused. *Note: Only report TACO, TRALI, AHTR, or Other reactions for recipients transfused by your facility.*
Is this reaction associated with an incident?	Optional. Select 'Yes' or 'No' if this reaction is associated with an incident.
If Yes, Incident Type:	Optional. Select all incident codes that apply to the recipient's reaction incident.
Was this reaction reported following a massive transfusion protocol?	**Required.** Select 'Yes', 'No', or 'Unknown' if the reaction was reported after a massive transfusion protocol.
Recipient Clinical Presentation	
Signs and symptoms	Optional. Select all signs and symptoms that the recipient has experienced. Refer to the NHSN Biovigilance Component Hemovigilance Module Protocol for glossary for definitions.
Other	Optional. Complete if the recipient displayed any signs and symptoms not listed above.
Recipient Treatment	
Did the recipient receive treatment for the transfusion reaction?	Optional. Indicate whether the recipient received treatment for the transfusion adverse reaction.
If yes, select treatments(s):	Optional. Indicate the type of treatment(s) provided in response to the transfusion adverse reaction. Select all that apply.
Select type of medication(s), volume resuscitation, respiratory support, renal replacement therapy, or phlebotomy	Optional. Complete if recipient received medication(s), volume resuscitation, respiratory support, renal replacement therapy, phlebotomy (to decrease blood volume) or other. Select the type of medication(s), volume resuscitation, respiratory support, or renal replacement therapy.

Data Field	Instructions for Form Completion
☐ Other, Specify	Optional. If other, specify the type of treatment.
Recipient Outcome	
Outcome	**Required.** Select the outcome of the transfusion recipient.
If death, date of death	**Required.** If the recipient died following the adverse reaction, enter the date of death whether the death was transfusion related.
If death, cause of death:	**Required.** Indicate the International Classification of Diseases (ICD) -10-CM code for the recipient's cause of death.
If recipient died, relationship of transfusion to death:	**Required.** Indicate the relationship between the transfusion and recipient's death by selecting 'Definite', 'Probable', 'Possible', 'Doubtful', 'Ruled Out', or 'Not Determined' using FDA criteria.
Transfused Component Details (recipient)	
Transfusion **Start** Date	**Required.** Enter the date the transfusion started.
Transfusion **Start** Time	**Required.** Enter the time the transfusion started using a 24-hour clock.
Transfusion **End** Date	**Required.** Enter the date the transfusion ended.
Transfusion **End** Time	**Required.** Enter the time the transfusion ended using a 24-hour clock.
ISBT-128 Component code	**Required.** Indicate the ISBT-128 component code for the product transfused using only the portion that identifies the product type.
Amount transfused at reaction onset	Optional. Indicate the amount transfusion at reaction onset.
☐ Entire unit	Select if the entire unit was transfused at reaction onset.
☐ Partial unit	Select if only part of the unit was transfused at reaction onset.
☐ Volume transfused _____mL	Complete if a partial unit was transfused. Indicate the volume transfused at reaction onset, use whole numbers (no decimals).
Donor Identification number (DIN)	**Required.** For all reaction types, enter the individual unit number as it appears on the product label. The sample ISBT-128 unit number would be entered as seen below.  W 0 0 0 0 0 7 1 2 3 4 5 6 0 0 D
Unit expiration date	**Required.** Enter the expiration date of the unit(s). The expiration date for the sample label below would be 02/11/2007. 

Data Field	Instructions for Form Completion
Unit expiration time	**Required.** Enter the expiration time of the unit(s). NHSN will auto fill this editable field to 23:59(11:59PM). The expiration time for the sample label below would be 15:20. 
Unit Blood group	**Required.** Select the blood group of the unit(s) transfused; enter **N/A** for products where blood group is not applicable.
Implicated unit?	**Required.** If a particular unit was implicated, the unit details must be entered by selecting 'Y' for yes, 'N' for no, or 'U' for unknown.
Laboratory Results (donor and recipient)	
Donor or Recipient	**Optional.** Indicate whether this test was performed on a donor specimen or recipient specimen.
Test name	**Optional.** Indicate the name of the test that was conducted on the donor or recipient specimen.
Collection date	**Optional.** Indicate the date that the test was performed on the donoror recipient specimen.
Test result	**Optional.** Indicate the test results from the test performed on the donor or recipient specimen.
Investigation Findings	
Adverse Reaction	**Required.** Indicate the adverse reactions experienced by the recipient. Select all that apply. ***Note:*** *Multiple adverse reactions can be reported per form. Report the reaction* ***after the investigation has been finalized****. Incomplete records can be saved until it is ready to be submitted. If new information becomes available at a later time, the record can be edited.*
If AHTR: Immune	Optional. Indicate the antibodies present within the recipient. Select all that apply.
If AHTR: Non-Immune	Optional. Select the process or condition that the recipient experienced.
Case Definition	**Required.** Refer to case definition in the NHSN Biovigilance Component Hemovigilance Module Protocol.
Severity	**Required.** Refer to severity classification in the NHSN Biovigilance Component Hemovigilance Module Protocol.
Imputability	**Required.** Refer to imputability classification in the NHSN Biovigilance Component Hemovigilance Module Protocol. *Note:* ***Doubtful*** *and* ***Ruled Out*** *need not be routinely reported.*
Facility Investigation Notes	
Facility Investigation Notes	Optional. Enter additional information about the incident.

Data Field	Instructions for Form Completion
Facility Investigation Status	**Required.** Select the status of this investigation. If report is marked as 'Complete', but some required fields are missing, include reasoning in 'Facility Investigation Notes' section.
CDC Case Management (to be completed by CDC staff)	
CDC Case Manager ID	This section will be completed by CDC staff only.
Report status	This section will be completed by CDC staff only.
CDC Case Management Notes	This section will be completed by CDC staff only.