Hemovigilance Module
Transfusion Transmitted Infection (TTI)
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.
Medical Record #	**Required.** List the facility's record number for the recipient.
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 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.
Ethnicity	Optional. Select the transfusion recipient's ethnicity.
Race	Optional. Indicate the transfusion recipient's race. Select all that apply.
Blood group	**Required.** 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 conditions present at the time of transfusion?	**Required.** Indicate if the recipient had sickle cell disease or thalassemia at the time of the transfusion.

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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 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 patient'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 Laboratory Testing	
Was a test to detect a specific pathogen performed on a recipient clinical sample that was collected pre-transfusion?	**Required**. Select 'Yes', 'No' or 'Pending' to indicate whether a test was performed on a recipient's clinical sample, collected pre-transfusion, to detect a specific pathogen.
If Yes, positive or reactive results?	**Required**. Indicated whether the test results were positive or reactive by selecting 'Yes', 'No', or 'Pending Results'.
Collection Date	**Required.** Indicate the date that the clinical sample was collected pre-transfusion.
Org1:	**Required.** Identify the organism that was detected.
Org2:	Optional. Identify the organism that was detected.
Org3:	Optional**.** Identify the organism that was detected.
Was a test to detect a specific pathogen performed on a recipient post-transfusion?	**Required**. Select 'Yes', No' or 'Pending' to indicate whether a test was performed on a recipient's clinical sample, collected post-transfusion, to detect a specific pathogen.
If Yes, positive or reactive results?	**Required**. Indicated whether the test results were positive or reactive by selecting 'Yes', 'No', or 'Pending Results'.

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Collection Date	**Required.** Indicate the date that the clinical sample was collected post-transfusion.
Org 1:	**Required.** Identify the organism that was detected.
Org2:	Optional. Identify the organism that was detected.
Org3:	Optional. Identify the organism that was detected.
Recipient Clinical Presentation	
Signs and symptoms	Optional. Select all signs and symptoms that the recipient is or has experienced. Refer to the NHSN Biovigilance Component Hemovigilance Module Surveillance Protocol for glossary for definitions.
Other	Optional. Complete if the recipient displayed any signs and symptoms not listed above.
Recipient Treatment	
Did the patient receive treatment for the transfusion reaction?	Optional. Indicate whether the recipient received treatment for the transfusion transmitted infection.
If yes, select treatment(s):	Optional. Indicate the type of treatment provided in response to the transfusion transmitted infection. Select all that apply.
Select type of medication(s), volume resuscitation, respiratory support, or renal replacement therapy	Optional. Complete if recipient received medication(s), volume resuscitation, respiratory support, or renal replacement therapy. Select the type of medication(s), volume resuscitation, respiratory support, or renal replacement therapy.
Other, Specify	Optional. Complete if recipient received another type of treatment not listed above. Specify the type of treatment.
Recipient Outcome	
Outcome	**Required.** Enter 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'. Refer to the NHSN Biovigilance Component Hemovigilance Module Surveillance Protocol for relationship of transfusion to death classifications.
Recipient Epidemiologic Risk Assessment	
Temporally associated unexplained clinical illness consistent with infection	Optional. Check box.

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Evidence of the pathogen in an additional recipient of a component from the same donation	Optional. Check box.
Related Recipient Report IDs:	Optional. List the Adverse Reaction IDs from the related recipient.
Animal exposure in the 30 days prior to symptom onset	Optional. Check box.
Mosquito exposure in the 30 days prior to symptom onset	Optional. Check box.
Tick exposure in the 30 days prior to symptom onset	Optional. Check box.
Exposure to individual exhibiting similar symptoms prior to symptom onset	Optional. Check box.
International travel in the 30 days before symptom onset	Optional. Check box.
International travel Country	Optional. Enter the country name that the recipient traveled to.
International travel Arrival Date	Optional. Enter the date that the recipient arrived at this country.
International travel Departure Date	Optional. Enter the date that the recipient departed from this country.
Domestic travel (outside of state of residence in the 30 days before symptom onset	Optional. Check box.
Domestic travel State	Optional. Enter the state name that the recipient traveled to.
Domestic travel Arrival Date	Optional. Enter the date that the recipient arrived in the state.
Domestic travel Departure Date	Optional. Enter the date that the recipient departed from the state.
Recipient has lived outside the U.S.?	Optional. Check box.
Country	Optional. Enter the country name that the recipient has resided in.
Arrival Date	Optional. Enter the date the recipient arrived at this country.
Departure Date	Optional. Enter the date that the recipient departed from this country.

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Recipient traveled outside the U.S. in the last two years?	Optional. Check box.
☐ Country	Optional. Enter the country name that the recipient traveled to.
☐ Arrival Date	Optional. Enter the date the recipient arrived at this country.
☐ Departure Date	Optional. Enter the date that the recipient departed from this country.
Transfused Component Details (recipient) *Report all transfused components within 30 days of symptom onset*	
Transfusion **Start** Date	**Required.** Enter the date the transfusion started.
Transfusion **Start** Time	Optional. Enter the time the transfusion started using a 24-hour clock.
Transfusion **End** Date	**Required.** Enter the date the transfusion ended.
Transfusion **End** Time	Optional. 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, in 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. Unit number is optional for all other adverse reactions. 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 *Note: The check digit is optional. If the check digit is entered, the system will verify that it is correct using an internal check digit calculator. If the check digit is not entered, the space will remain blank.*
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. 

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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 on the first row and this box will be checked. If no unit can be implicated, these boxes will be inactive.
Unit tested?	Optional.
Pathogen Detected?	Optional.
Pathogen	Optional. Report pathogens detected in component. If more than three, notify HV team.
Blood Product/ Donor Investigation	
Was a test to detect a specific pathogen performed on the donor pre-donation?	**Required.** Select 'Yes', 'No', 'Pending', or 'Unknown' to indicate whether a test was performed on the donor's pre-donation to detect a specific pathogen.
If Yes, positive or reactive results?	**Required.** Indicated whether the test results were positive or reactive by selecting 'Yes', 'No', or 'Pending'.
Collection Date	**Required.** Indicate the date that the donor's sample was collected pre-donation.
Org 1	**Required.** Identify the organism that was detected.
Org2:	Optional. Identify the organism that was detected.
Org3:	Optional**.** Identify the organism that was detected.
Was a test to detect a specific pathogen performed on the donor post-donation?	**Required.** Select 'Yes', 'No', 'Pending', or 'Unknown' to indicate whether a test was performed on the donor's post-donation to detect a specific pathogen.
If Yes, positive or reactive results?	**Required.** Indicated whether the test results were positive or reactive by selecting 'Yes', 'No', or 'Pending Results'.
Collection Date	**Required.** Indicate the date that the donor's sample was collected post-donation.
Org 1	**Required.** Identify the organism that was detected.
Org2:	Optional. Identify the organism that was detected.
Org3:	Optional**.** Identify the organism that was detected.
Investigation Findings	
Adverse Reaction	Auto populated as Transfusion Transmitted Infection.

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Case definition	**Required.** Refer to case definition in the NHSN Biovigilance Component Hemovigilance Module Surveillance Protocol.
Severity	**Required.** Refer to severity classification in the NHSN Biovigilance Component Hemovigilance Module Surveillance Protocol.
Imputability	**Required.** Refer to imputability classification in the NHSN Biovigilance Component Hemovigilance Module Surveillance Protocol.
Facility/ Health Department Investigation Notes	
Facility Investigation Notes	Optional. Enter additional information about the incident.
Facility/ Health Department 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 Investigation (to be completed by CDC staff)	
CDC Investigator ID	This section will be completed by CDC staff only.
TTI Rapid Alert Report ID	This section will be completed by CDC staff only.
Was FDA notified?	This section will be completed by CDC staff only.
Was the blood supplier notified of this adverse reaction?	This section will be completed by CDC staff only.
Was a traceback conducted?	This section will be completed by CDC staff only.
CDC SME Group notified?	This section will be completed by CDC staff only.
CDC SME Case ID	This section will be completed by CDC staff only.
State health department notified?	This section will be completed by CDC staff only.
Report status	This section will be completed by CDC staff only.
CDC Investigation Notes (to be completed by CDC staff)	
This section will be completed by CDC staff only.	