

Transfusion-Associated Infections **Instructions for completing the generic investigation form**

CDC developed the generic ***Transfusion-Associated Infections*** form (and these instructions) to facilitate investigating and tracking potential transfusion-associated cases of infection (e.g., by public health departments). The form provides a broadly applicable framework for transfusion investigations; for example, it includes tables for tracking and recording information about blood donors, donations, transfusions, and recipients.

The generic investigation form is not an OMB (Office of Management and Budget)–approved report form. As such, the form can be modified to suit the needs of the user and the particulars of the case at hand, and it can be used in combination with other applicable/available forms. For example, selected tables on the generic form could be used to supplement a disease-specific module (e.g., CDC’s ***Transfusion-Associated Babesiosis*** form).

Well-coordinated investigations among public health agencies, blood centers, transfusion services, clinicians, and laboratorians are strongly encouraged. CDC can be consulted regarding all aspects of diagnosing, treating, and investigating cases.

The form is largely self-explanatory; however, some instructions are provided below to assist in completing the form.

In the instructions, all page numbers refer to those in the form. Depending on the trigger for the investigation, begin either with the ***Recipient Investigation*** section (pages 1 and 2) or the ***Donor Investigation*** section (pages 3 and 4). If a donor(s) is ‘implicated’ (e.g., by laboratory and epidemiologic criteria), consider/investigate the possibility that other recipients linked to the same donor (either the same or a different donation) became infected.

Throughout the form, **approximate dates are acceptable (mm/yyyy)**, if precise dates are not available.

Transfusion-Associated Infections: Recipient Investigation (pages 1 & 2)

Date completed:

Indicate the date this section of the form (Recipient Investigation) was completed.

Investigation #:

At the top of each page of the form, space is provided to record an identification number for the transfusion investigation. In addition, as noted below, space is provided on pages 1 and 3 for Case ID#'s and other identifiers for recipient(s) and donor(s), respectively.

Categorization:

The categories (Definite, Probable, etc.) provided on **page 1** are intended to help assess the likelihood that a case of infection was transfusion associated (<http://www.cdc.gov/nhsn/PDFs/Biovigilance/BV-HV-protocol-current.pdf>, Page 18 of 27, January 2013). These categories are adapted from **National Healthcare Safety Network (NHSN)**, a voluntary, internet-based surveillance system that integrates patient and healthcare personnel safety surveillance systems managed by CDC's Division of Healthcare Quality Promotion. NHSN also includes a component for **hospitals** to monitor adverse reactions and incidents associated with transfusions. In this context, NHSN developed generic criteria for classifying the likelihood that a case of infection was transfusion associated.

All case criteria (including pathogen/disease-specific criteria) are dependent on laboratory expertise and epidemiologic/clinical judgment. In addition, the strength of evidence that a case was transfusion associated might change as the investigation proceeds and more information becomes available.

Pathogen:

Specify the pathogen (or suspected pathogen, if not yet confirmed). If known, provide both the genus and species (e.g., *Babesia microti*). Of note, consider using a disease-specific module, if available (e.g., CDC's ***Transfusion-Associated Babesiosis*** form).

Form completed by:

Provide contact information for the primary person who completed this form/section, even if multiple persons within your agency, as well as other agencies, collaborated in the investigation. If applicable, in the donor section (page 3), a different person can be specified.

Date reported to the investigator/agency:

Provide the date (or approximate time) this recipient/patient first came to the attention of the investigator/agency. If applicable, in the donor section (page 3), a different date can be specified.

Reported by:

Provide contact information for the relevant person/agency (e.g., physician or blood collection agency). If applicable, in the donor section (page 3), a different person/agency can be specified.

Indicate if the information in this section applies to the **initial (index) recipient** or to an **additional (non-index) recipient**, if any, linked to the same donor—either the same or different donations. We recommend completing a separate copy of the **Recipient Investigation** section for each pertinent recipient, even though some questions might be more applicable to the index recipient.

Case ID#:

This space is provided to record a case number or another unique ID.

Demographics:

To facilitate tracking and differentiating among recipients, provide whatever basic demographic information is available, in accordance with privacy protection laws. Record **name** (or another unique identifier), **address**, contact information, and **date of birth** (or mm/yyyy). Indicate the recipient's **age** at the time of the relevant transfusion(s); and specify if the age is provided in days, months, or years. For **race**, select all that apply.

Clinical information

Date of symptom onset:

Indicate the onset date of clinical manifestations thought, in retrospect, to be attributable to the infection; this date might precede the date of diagnosis by a considerable amount of time. If asymptomatic, mark 'Not applicable.' Mark 'Unknown,' if this information is not available or is not even estimable (e.g., because the patient had comorbidities or altered mental status).

Clinical manifestations, if any:

See previous question. If applicable, specify the potentially relevant clinical manifestations. Use the *Notes* section (page 2) to provide more details.

Diagnostic testing

When available, a disease-specific module (e.g., CDC's *Transfusion-Associated Babesiosis* form), may have a similar table with greater detail for diagnostic testing. If so, the table in the disease-specific module can be used.

Date of diagnosis

If applicable, provide the date the recipient's case was explicitly diagnosed. For non-index recipients, there may not be a date of diagnosis.

Were any pre-transfusion specimens tested for evidence of infection?

Specify if the recipient was tested for evidence of infection before the transfusion or if a pre-transfusion specimen was still available and has since been tested.

If yes, what was overall result of the testing?

Indicate whether evidence of pre-transfusion infection was detected, by specifying the overall result of the testing (positive, negative, indeterminate, or unknown); use the space on the next line of the form to provide more details (see '**result**' below).

Test type(s):

Specify type of test (e.g., blood smear, indirect fluorescent antibody [**IFA**] assay, polymerase chain reaction [**PCR**]).

Result(s) (e.g., titer):

Provide available details that are applicable to the test (e.g., titer, species, parasitemia level). (See above regarding ‘**overall result.**’)

Testing facility:

Provide details about the laboratory that actually performed this testing (rather than a facility that collected the specimen but shipped it elsewhere). Indicate in the table or the *Notes* section (page 2) if multiple laboratories conducted testing (e.g., a commercial laboratory and CDC).

Were any post-transfusion specimens tested for evidence of infection?

Date of collection:

Specify date of collection, which might differ from the date(s) of testing. Use the *Notes* section (page 2) to provide more details.

Date of testing:

Specify date the testing was performed. Indicate in the table or the *Notes* section (page 2) if the testing was performed on multiple days (e.g., initial vs. retrospective testing). If pertinent, also indicate the date the results were reported (i.e., became available).

Specimen:

Specify type of specimen (e.g., whole blood or serum).

Test type:

Specify type of test (e.g., blood smear, indirect fluorescent antibody [**IFA**] assay, polymerase chain reaction [**PCR**]).

Result:

Specify overall result (positive, negative, indeterminate, or unknown). If available, provide more details (e.g., titer or species) in the table or the *Notes* section (page 2).

Testing facility:

Provide details about the laboratory that actually performed this testing (rather than a facility that collected the specimen but shipped it elsewhere). Indicate in the table or the *Notes* section (page 2) if multiple laboratories conducted testing (e.g., a commercial laboratory and CDC).

Did the patient receive treatment for this infection?

If applicable, use the *Notes* section (page 2) to provide more details about antimicrobial or other therapy, as well as the clinical context.

Risk factors

Did the recipient have possible routes of exposure other than transfusion?

If yes, describe potential exposures, including where and when they may have occurred. Use the *Notes* section (page 2) to provide more details/perspective, to help assess the relative possibility and plausibility of various routes of transmission.

Current status:

Specify the patient's status. If the patient died, provide the date of death; indicate whether an autopsy was performed; and, even if it was not, indicate if the infection might have contributed to or caused the death.

Transfusion history

Some recipients might have been multiply transfused over a short or extended period; a large number of donors may need to be investigated. The timeframe to consider and the relevant blood products depend in part on the pathogen and host factors.

Reason(s) for transfusion(s):

Specify the reason(s) the recipient was transfused. Use the *Notes* section (page 2) to provide more details/perspective (e.g., the proximal and underlying reasons/comorbidities).

For each potentially relevant transfusion, specify in the table the **type of product** (e.g., red blood cells or platelets), the **date of transfusion**, the **transfusion facility** (where the transfusion occurred), the **blood supplier**, and the **Blood Product Unit Number** (the identifier used to track the product/component). If needed, use *Recipient Investigation: Additional Sheet*.

Every blood donation has a unique identifying number (**whole blood number, or WBN**). A blood donation may be separated into multiple blood products (e.g., red blood cells or platelets), each of which has a different **Blood Product Unit Number**. Depending on the pathogen, only particular types of blood products/components might be relevant or particular types might pose a higher risk than others.

Donor tracking

In the first column of this table, record each of the **Blood Product Unit Numbers** listed in the last column of the previous table. Then track each unit number: Specify the **blood bank/center**, the **date of donation**, the status of the pertinent **donor** (whether **located/tested**), details about **donor testing (test type and results;** see instructions above), and conclusions regarding that donor (**donor 'implicated?'**).

For each potentially relevant donor, complete the *Donor Investigation* section (pages 3 and 4), to record more information about the donor (e.g., demographic and additional laboratory data) and to facilitate identifying/tracking other recipients linked to the donor—either the same or different donations.

Facility(ies) where 'implicated' transfusion(s) occurred:

If applicable, provide additional details about the transfusion facility(ies), including for a point of contact. Additional space is available in the *Notes* section that follows.

Notes:

This section can be used to record additional test results and other information about this recipient—e.g., factors that affect the possibility and plausibility of various routes of transmission.

Transfusion-Associated Infections: Donor Investigation (pages 3 & 4)

Date completed:

Indicate the date this section of the form (Donor Investigation) was completed. If applicable, a different date can be specified in the header in the recipient section (pages 1 & 2).

Investigation #:

At the top of each page of the form, space is provided to record an identification number for the transfusion investigation. In addition, space is provided on pages 1 and 3 for Case ID#'s and other identifiers for recipient(s) and donor(s), respectively.

Pathogen:

Specify the pathogen (or suspected pathogen, if not yet confirmed). If known, provide both the genus and species (e.g., *Babesia microti*). Of note, consider using a disease-specific module, if available (e.g., CDC's *Transfusion-Associated Babesiosis* form).

Form completed by:

Provide contact information for the primary person who completed this form/section, even if multiple persons within your agency, as well as other agencies, collaborated in the investigation. If applicable, in the recipient section (page 1), a different person can be specified.

Date reported to the investigator/agency:

Provide the date (or approximate time) this donor first came to the attention of the investigator/agency. If applicable, in the recipient section (page 1), a different date can be specified.

Reported by:

Provide contact information for the relevant person/agency (e.g., physician or blood collection agency). If applicable, in the recipient section (page 1), a different person/agency can be specified.

ID#:

This space is provided to record a case number or another unique ID.

Demographics:

To facilitate tracking and differentiating among donors, provide whatever basic demographic information is available, in accordance with privacy protection laws. Record **name** (or another unique identifier), **address**, contact information, and **date of birth** (or mm/yyyy). Indicate the donor's **age** at the time of the index donation (*donation associated with the index recipient*). For **race**, select all that apply.

Clinical information

Date of symptom onset:

Indicate the onset date (or approximate timing) of potentially relevant clinical manifestations, if any, that occurred either before or after the relevant donation(s). If asymptomatic, mark 'Not applicable.' Mark 'Unknown,' if this information is not available.

Clinical manifestations, if any:

See previous question. If applicable, specify the potentially relevant clinical manifestations. Use the *Notes* section (page 4) to provide more details.

Diagnostic testing

Date of collection:

For example, if a segment (pigtail or retention tube) or cocomponent was available for testing, the date of collection would be the date of donation. Use the *Notes* section (page 4) to provide more details.

Date of testing:

Specify the date the testing was performed, which might be long after a specimen (e.g., a segment) was collected. If pertinent, also indicate the date the results were reported (i.e., became available).

Specimen:

Specify type of specimen (e.g., whole blood or serum).

Segment/Cocomponent:

Indicate if this specimen was part of a retained segment or cocomponent from the pertinent donation or from a previous or subsequent donation (vs. a specimen collected as part of an investigation). If yes, provide additional details in the space provided below the table.

Test type:

Specify type of test (e.g., blood smear, indirect fluorescent antibody [IFA] assay, polymerase chain reaction [PCR]).

Result:

Specify overall result (positive, negative, indeterminate, or unknown). If available, provide more details (e.g., titer or species) in the table or the *Notes* section (page 4).

Testing facility:

Provide details about the laboratory that actually performed this testing (rather than a facility that collected the specimen but shipped it elsewhere). Indicate in the table or the *Notes* section (page 4) if multiple laboratories conducted testing (e.g., a commercial laboratory and CDC).

Testing details

See above. Use this space to provide additional details about the testing, including types of segments/components and the test results.

Risk factors

Did the donor have risk factors for infection with the pathogen?

If yes, describe potential exposures, including where and when they may have occurred. Use the *Notes* section (page 4) to provide more details.

Donation history

The timeframe to consider and the relevant blood products depend in part on the pathogen and host factors.

Date of donation:

Indicate when it occurred.

Donation facility:

Indicate where it was collected.

Blood Product Unit Number:

Specify the identifier used to track the product/component.

Type of product:

Specify the pertinent product/component (e.g., red blood cells or platelets).

Transfused?

Indicate whether it was transfused. Complete the table that follows for each transfused product.

Recipient tracking

For each transfused product (see last column in previous table), record the **Blood Product Unit Number** and the **type of product** (from the 3rd and 4th columns in the previous table). Then specify the **date of transfusion**, the **transfusion facility** (where the transfusion occurred), and a unique **recipient identifier** (see page 1 of the form for various options). If needed, additional recipients can be tracked on the *Donor Investigation: Additional Sheet*.

Diagnostic testing for recipient(s)

In the first column of this table, record each of the **recipient identifiers** listed in the last column of the previous table. Then track/record details about recipient testing: Specify the **date of collection**, the **date of testing**, the **specimen** (e.g., whole blood or serum), **test type** (e.g., blood smear, indirect fluorescent antibody [**IIFA**] assay, polymerase chain reaction [**PCR**]), the **result** (e.g., overall result [positive, negative, indeterminate] and additional details [titer or species]), and the **testing facility** (i.e., the laboratory that actually performed this testing rather than a facility that collected the specimen but shipped it elsewhere). Complete a copy of the *Recipient Investigation* section for each pertinent recipient.

Notes:

This section can be used to record additional test results and other information about this donor—e.g., factors that affect the possibility and plausibility that the donor was infected at the time of the pertinent donation(s).