**1. RECIPIENT IDENTIFICATION**

<table>
<thead>
<tr>
<th>LAST NAME</th>
<th>FIRST NAME</th>
<th>HEALTH CARD NUMBER</th>
<th>HOSPITAL CARD NUMBER</th>
<th>Date of Birth: Day</th>
<th>Month</th>
<th>Year</th>
<th>Sex: Male</th>
<th>Female</th>
<th>Other</th>
<th>Unknown</th>
</tr>
</thead>
</table>

**2. CLINICAL HISTORY**

- **Blood Group:**
  - AB: [ ] A [ ] B [ ] O [ ] AB
  - Rh: [ ] Pos [ ] Neg

- **Pregnancies/Miscarriages:**
  - Yes <3 mo. [ ] Yes >3 mo. [ ] No [ ] Unknown

- **Transfusions:**
  - Yes <3 mo. [ ] Yes >3 mo. [ ] No [ ] Unknown

- **Immune-Compromised:**
  - Yes [ ] Describe: 
  - No [ ]

**3. DATE, TIME AND PLACE OF INCIDENT / ADVERSE REACTION**

- **Date and time occurred:**
  - Day [ ] Month [ ] Year [ ] Time (hh:mm)
- **Date and time reported:**
  - Day [ ] Month [ ] Year [ ] Time (hh:mm)

**3a. Incident Information**

- [ ] Patient Identification Incident-------Specify: 
- [ ] Product Related Incident -------Specify: 
- [ ] Equipment Related Incident-------Specify: 
- [ ] Other Incident ---------------------Specify: 

**3b. Premedication and Anesthesia**

- Pre-medication: [ ] Yes [ ] No
  - Specify drug/dose/route:

**3c. Report of Possible Transfusion Related Bloodborne Infection**

- [ ] Viral Infection
- [ ] Other Infection

**4. CLINICAL SIGNS AND LABORATORY RESULTS**

**4a. Clinical Signs and Symptoms**

- [ ] No Clinical Sign/Symptom
- [ ] Temperature -------before: ___ after: ___
- [ ] Pulse -------before: ___ after: ___
- [ ] Respiration -------before: ___ after: ___
- [ ] Blood Pressure -------before: ___ after: ___

**Clinical Information for TRALI:**

- Chest X-ray Results: [ ] Bilateral Infiltrates [ ] Other ------- Describe: 
- Evidence of Circulatory Overload: [ ] Yes [ ] No
  - Explain: 
- Hospital Sample Collection to be sent to blood supplier centre – please see reverse for instructions

**4b. Abnormal Tests/Laboratory Results**

- **Name of Laboratory Tests:**
  - Date Specimen Taken (ddmmmyyyy) 
  - Results
    - Positive [ ] Negative [ ] Elevated [ ] Decreased [ ]
- **Blood Culture Results:**
  - Date/Time Specimen Taken (ddmmmyyyy) (hh:mm) 
  - # of Positive [ ] Negative [ ]
  - If positive, specify organism(s) identified (genus/species) 
  - Unit no. or Lot no. 

---

**FACILITY IDENTIFICATION**

<table>
<thead>
<tr>
<th>NAME OF FACILITY</th>
<th>HOSPITAL CODE</th>
<th>CITY</th>
<th>PROVINCE</th>
</tr>
</thead>
</table>

**PUBLIC HEALTH**

Agency of Canada

F100_V3.0E (November 2007) 
Disponible en français
### 5. SUSPECT BLOOD, BLOOD COMPONENTS, OR BLOOD PRODUCTS (PLASMA DERIVATIVES)

<table>
<thead>
<tr>
<th>Transfused blood, blood components, or blood products (plasma derivatives)</th>
<th>Group of unit</th>
<th>Blood Supplier centre code*</th>
<th>Unit no. or Lot no.</th>
<th>Expiry date (ddmmmyyyy)</th>
<th>Amount administered</th>
<th>Transfusion Started</th>
<th>Transfusion Finished</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
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</tr>
</tbody>
</table>

### 6. MEASURES TAKEN

- None
- Transfusion Stopped
- Transfusion Restarted
- Antipyretics
- Analgesics
- Antihistamines
- Steroids
- Diuretics
- Vasopressors
- Antibiotics
- Supplementary O₂
- Mechanical Ventilation
- ICU Required
- Blood Culture
- Product Culture

### 7. RESULTS OF INVESTIGATION & CONCLUSION

- No Transfusion Reaction
- Allergic Reaction:
  - Minor
  - Severe Anaphylactic/Anaphylactoid
  - Anaphylactic Shock
- Febrile Non-Hemolytic Reaction
- Incompatible Transfusion:
  - Unintentional
  - Intentional
  - ABO System Specify:
  - Other System Specify:
- Hemolytic Reaction:
  - Acute
  - Delayed
- Delayed Serological Transfusion Reaction (new alloantibodies) Specify:

- Bacterial Infection
- Viral Infection
- Other Infection
- Donor:
  - Infected
  - Uninfected
  - Unknown

Specify type of infection:
### 1. RECIPIENT IDENTIFICATION

<table>
<thead>
<tr>
<th>LAST NAME</th>
<th>FIRST NAME</th>
<th>SEX</th>
<th>MO.</th>
<th>YEAR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>HEALTH CARD NUMBER</th>
<th>HOSPITAL CARD NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date of Birth:</th>
<th>Day</th>
<th>Month</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 7. RESULTS OF INVESTIGATION & CONCLUSION (CONTINUED)

#### Relationship of Adverse Event to Transfusion:
- [ ] Definite
- [ ] Probable
- [ ] Possible
- [ ] Doubtful
- [ ] Ruled Out
- [ ] Not Determined

#### Severity of Adverse Event:
- [ ] Grade 1 (Non-Severe)
- [ ] Grade 2 (Severe)
- [ ] Grade 3 (Life-threatening)
- [ ] Grade 4 (Death)
- [ ] Not Determined

**Description:**

**Outcome of Adverse Event:**
- [ ] Death
- [ ] Major or Long-Term Sequelae
- [ ] Minor or No Sequelae
- [ ] Not Determined

#### Relationship of transfusion to recipient's death:
- [ ] Definite
- [ ] Doubtful
- [ ] Probable
- [ ] Ruled Out
- [ ] Possible
- [ ] Not Determined

### 8. COMMENTS

**Reporting Physician or Designate:**

**Telephone Number:** ( )

**Date & Time:** Day Month Year Time (hh:mm)

### 9. COMMENTS – COMPLETED BY CANADIAN BLOOD SERVICES (CBS)

**CBS Medical Director:**

**Telephone Number:** ( )

**Date & Time:** Day Month Year Time (hh:mm)
2. CLINICAL HISTORY

Standardized List for the patient diagnosis/category:

- Hematology/Bone Marrow Transplant
- Oncology
- Medical
- Surgical
- Obstetrics/Gyne/Perinatal
- Trauma
- Neonatal

3. DATE, TIME AND PLACE OF INCIDENT / ADVERSE REACTION

Place of Incident/Adverse Reaction

<table>
<thead>
<tr>
<th>ICU</th>
<th>Intensive Care Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All intensive care units including i.e. neonatal, special care nursery, neuro, medical, burn unit</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ER</th>
<th>Emergency</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Emergency and/or Trauma areas</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MSW</th>
<th>Medical/Surgical Ward</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All inpatient care areas within a facility i.e. medical ward, surgical, hematology</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>OB</th>
<th>Obstetrics</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Obstetrics including labour and delivery, case room and birth centre</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>OR</th>
<th>Operating Room</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Operating room including day surgery</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>REC</th>
<th>Recovery Room</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Recovery Room including post anesthesia recovery</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CHR</th>
<th>Chronic Care</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chronic Care refers to long term care facilities/units</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>OP</th>
<th>Outpatient Clinic</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Outpatient refers to ambulatory care areas, medical day units, essentially where outpatients would come to receive a transfusion during daylight working hours</td>
</tr>
</tbody>
</table>

4. CLINICAL SIGNS AND LABORATORY RESULTS

Hospital Sample Collection to be sent to blood supplier centre:

**Call** your local blood supplier centre to obtain the most up-to-date shipping and sample requirements.

**For**

- patient samples
- transfused unit(s) sample(s) when available
- crossmatch testing samples (time-sensitive samples)

5. SUSPECT BLOOD, BLOOD COMPONENTS, OR BLOOD PRODUCTS (PLASMA DERIVATIVES)

**Product Modification Codes**

- IRR: Irradiated
- CMV: Negative for anti-CMV
- D: Deglycerolized
- DV: Divided
- LV: Low volume
- PR: Plasma reduced
- W: Washed
- P: Pooled
- T: Thawed

**Blood Supplier Centre Codes**

Please refer to your local Canadian Blood Services or HÉMA-QUÉBEC codes.
7. RESULTS OF INVESTIGATION & CONCLUSION

Definition of Transfusion Associated Dyspnea (TAD)

TAD is characterized by respiratory distress within 24 hours of transfusion that does not meet the criteria of TRALI, TACO, or allergic reaction. Respiratory distress should not be explained by the patient's underlying condition.

Definition of Transfusion Related Acute Lung Injury (TRALI)

- In patients with no evidence of Acute Lung Injury (ALI) prior to transfusion, TRALI is diagnosed if:
  - New ALI is present:
    - Acute onset
    - Hypoxemia
      - $\text{PaO}_2 / \text{FiO}_2 \leq 300$ or
      - Oxygen saturation is $< 90\%$ on room air or
      - Other clinical evidence
    - Bilateral lung infiltrates on frontal chest x-ray
    - No evidence of circulatory overload
    - It occurs during, or within 6 hours of completion of transfusion
    - There are no other risk factors for ALI

Definition of Possible Transfusion Related Acute Lung Injury

- In patients with no evidence of ALI prior to transfusion, possible TRALI is diagnosed if:
  - New ALI is present:
    - Acute onset
    - Hypoxemia
      - $\text{PaO}_2 / \text{FiO}_2 \leq 300$ or
      - Oxygen saturation is $< 90\%$ on room air or
      - Other clinical evidence
    - Bilateral lung infiltrates on frontal chest x-ray
    - No evidence of circulatory overload
    - It occurs during, or within 6 hours of completion of transfusion
    - There are one or more risk factors for ALI:
      - Predisposing factors for ALI include:
        - Direct Lung Injury
          - Aspiration
          - Pneumonia
          - Toxic inhalation
          - Lung contusion
          - Near drowning
        - Indirect Lung Injury
          - Severe sepsis
          - Shock
          - Multiple trauma
          - Burn injury
          - Acute pancreatitis
          - Cardiopulmonary bypass
          - Drug overdose
### Relationship of Adverse Event to Transfusion

- **Definite**
  - Select "Definite" if a clinical and/or laboratory event occurred within a time period consistent with the administration of the blood, blood component, or blood product (plasma derivative) and did not seem to be explainable by any other cause.
  - Bacterial contamination is considered "Definite" if it meets all of the following criteria:
    - The same bacteria are found in the recipient and the blood, blood component, or blood product (plasma derivative).
    - Contamination of the blood sample or laboratory contamination is not suspected.

- **Probable**
  - Select "Probable" if a clinical and/or laboratory event occurred within a time period consistent with the administration of the blood, blood component, or blood product (plasma derivative) but did not seem to be explainable by any other cause.
  - Bacterial contamination is considered "Probable" if it meets the following criteria:
    - Positive blood, blood component, or blood product (plasma derivative) culture.
    - Contamination of the blood sample or laboratory contamination is not suspected.
    - The recipient presents signs and symptoms of sepsis (nothing else explains it).
    - The recipient's blood culture was not done.
      - No specimen was available.
      - A blood culture was not ordered.
    - The recipient’s blood culture is negative.
      - The recipient is already taking antibiotics.

- **Possible**
  - Select "Possible" if the clinical and/or laboratory event occurred within a time period consistent with the administration of the blood, blood component, or blood product (plasma derivative) but could also be explained by a concurrent disease or by the administration of a drug or other agent.
  - Bacterial contamination is considered "Possible" if it meets the following criteria:
    - The recipient's blood culture is positive.
    - The recipient presents signs and symptoms of sepsis (nothing else explains it).
    - A blood, blood component, or blood product (plasma derivative) culture was not done.
      - No specimen was available.
      - A blood culture was not ordered.

- **Doubtful**
  - Select "Doubtful" if the clinical or laboratory event occurred within a reasonable time period but the preponderance of data supports an alternative explanation.
  - Bacterial contamination is considered "Doubtful" if:
    - The blood, blood component, or blood product (plasma derivative) culture is positive for one pathogen and the recipient's blood culture is positive for a different pathogen, or the blood, blood component, or blood product (plasma derivative) culture is positive or the recipient's blood culture is positive but contamination of the sample or laboratory specimen is suspected.

- **Ruled out**
  - Select "Ruled Out" if the clinical and/or laboratory event occurred within a time period inconsistent with the administration of the blood, blood component, or blood product (plasma derivative) or, if it occurred within a consistent time period and it was proven to have no relationship to the transfusion.

- **Not Determined**
  - Select "Not Determined" if it remains to be determined whether the event was related to the administration of the blood, blood component, or blood product (plasma derivative) and further information is forthcoming.

### Severity of Adverse Event

- **Grade 1 (Non-Severe)**
  - Select “Grade 1 (Non-Severe)” if the recipient may require medical intervention (e.g. symptomatic treatment) but lack of such would not result in permanent damage or impairment of a body function.

- **Grade 2 (Severe)**
  - Select “Grade 2 (Severe)” if:
    - the recipient requires in-patient hospitalization or prolongation of hospitalization directly attributable to the event;
    - the adverse event results in persistent or significant disability or incapacity; or
    - the adverse event necessitates medical or surgical intervention to preclude permanent damage or impairment of a body function.

- **Grade 3 (Life-threatening)**
  - Select “Grade 3 (Life-threatening)” if the recipient required major intervention following the transfusion (vasopressors, intubation, transfer to intensive care).

- **Grade 4 (Death)**
  - Select “Grade 4 (Death)” if the recipient’s death was suspected to be the consequence of a transfusion reaction.

- **Not determined**
  - Select “Not determined” if the consequences of the transfusion reaction are not certain.

### Outcome of Adverse Event

- **Death**
  - Select “Death” if the recipient died.

  - **Relationship of Transfusion to Recipient's Death**
    - Document the relationship of the transfusion to the recipient's death by selecting one of the following:
      - **Definite**
        - Select "Definite" if the recipient's death occurred within a time period consistent with the administration of the blood, blood component, or blood product (plasma derivative) and was proven by investigation to have been caused by transfusion.
      - **Probable**
        - Select "Probable" if the recipient's death occurred within a time frame consistent with the administration of the blood, blood component, or blood product (plasma derivative) and did not seem to be explainable by any other cause.
      - **Possible**
        - Select "Possible" if the death occurred within a time period consistent with the administration of the blood, blood component, or blood product (plasma derivative) but could be explained by a concurrent disease or by the administration of a drug or other agent.
      - **Doubtful**
        - Select "Doubtful" if the death occurred within a reasonable time period in relation to the transfusion but the preponderance of data supports an alternative explanation.
      - **Ruled Out**
        - Select "Ruled Out" if the death occurred within a time period inconsistent with the administration of the blood, blood component, or blood product (plasma derivative) or, if it occurred within a consistent time period, but was proven to have no relationship to the transfusion.
      - **Not Determined**
        - Select "Not Determined" if it cannot be determined if the recipient’s death was related to the transfusion.

- **Major or Long-Term Sequelae**
  - Select “major or long term sequelae” if the recipient developed either an infection with a persistent infectious agent (HIV, Hepatitis C, Hepatitis B), or a transfusion reaction with major or long term sequelae or the anticipation of difficulties with future transfusions (e.g. development of antibodies to antigens present in more than 95% of donations).

- **Minor or No Sequelae**
  - Select “Minor or No Sequelae” if the recipient had no sequelae or permanent disability from the reaction or developed antibodies to low or medium frequency antigens (<95%) or other minor reactions.

- **Not Determined**
  - Select “Not Determined” if the outcome of the adverse event is not certain.