Case ID: _____

CANADIAN TRANSFUSION ADVERSE EVENT REPORTING FORM

☐ INCIDENT **(Complete sections 1,3,& 6 before & complete all sections during/after)**
☐ ADVERSE REACTION **(Complete all sections)**

PRODUCT TRANSFUSED ☐ YES ☐ NO

FACILITY IDENTIFICATION

NAME OF FACILITY	HOSPITAL CODE	CITY	PROVINCE

1. RECIPIENT IDENTIFICATION

LAST NAME | FIRST NAME

HEALTH CARD NUMBER | HOSPITAL CARD NUMBER

Date of Birth: Day / Month / Year

Sex: ☐ Male ☐ Other ☐ Female ☐ Unknown

2. CLINICAL HISTORY

Blood Group: **ABO:** ☐ 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: _____

Patient Diagnosis/Category: _____
Please see reverse for categories.

☐ Other Clinical History ····· Describe: _____

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

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

Place **occurred**: ☐ ICU ☐ ER ☐ MSW ☐ OB ☐ OR ☐ REC ☐ CHR ☐ OP
Please see reverse for definitions.

3a. Incident Information

☐ Patient Identification Incident ····· Specify: _____

☐ Product Related Incident ····· Specify: _____

☐ Equipment Related Incident ····· Specify: _____

☐ Other Incident ····· Specify: _____

3b. Premedication and Anesthesia

Premedication: ☐ Yes ····· ☐ No

Specify drug/dose/route:

Transfused under anesthesia: ☐ General ☐ Local/regional ☐ None

3c. Report of Possible Transfusion Related Blood Borne Infection

☐ Bacterial 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: ____

☐ Chills/rigors
☐ Urticaria
☐ Other skin rash
☐ Shortness of breath
☐ Hypoxemia ····· O_2 sat: ____
☐ Nausea/vomiting

☐ Pain ····· Specify: _____
☐ Jaundice
☐ Hemoglobinuria
☐ Oliguria
☐ Diffuse Hemorrhage
☐ Shock
☐ Other ····· Specify: _____

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 – *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	# of Negative	If positive, specify organism(s) identified (genus/species)	Unit no. or Lot no.
For culture performed on **recipient** post transfusion						
For culture performed on the **product**						

1. RECIPIENT IDENTIFICATION

LAST NAME | FIRST NAME

HEALTH CARD NUMBER | HOSPITAL CARD NUMBER

Date of Birth: Day | Month | Year

Sex: ☐ Male ☐ Female ☐ Other ☐ Unknown

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

Transfused blood, blood components, or blood products (plasma derivatives)								Amount administered			Transfusion Started		Transfusion Finished	
	Product modification*		Group of unit		Supplier centre code*						Date	Hour	Date	Hour
Product code/name	Hospital	Supplier	ABO	Rh		Unit no. or Lot no.	Expiry date (ddmmmyyyy)	Amount	Unit of measure	Fraction	(ddmmmyyyy)	(hh:mm)	(ddmmmyyyy)	(hh:mm)

Comments:

*Please see reverse for definitions.

6. MEASURES TAKEN

- ☐ None
- ☐ Transfusion Stopped
- ☐ Transfusion Restarted
- ☐ Antipyretics
- ☐ Analgesics
- ☐ Antihistamines
- ☐ Steroids
- ☐ Diuretics → ☐ Effective
- ☐ Vasopressors
- ☐ Antibiotics
- ☐ Supplementary O_2
- ☐ Mechanical Ventilation → duration: _____
- ☐ ICU Required
- ☐ Chest x-ray
- ☐ Blood Culture
- ☐ Product Culture
- ☐ Other Measures Taken → Specify:

7. RESULTS OF INVESTIGATION & CONCLUSION

☐ No Transfusion Reaction

☐ Febrile Non-Hemolytic Reaction

Allergic Reaction: ☐ Minor ☐ Severe Anaphylactic/Anaphylactoid ☐ Anaphylactic Shock

Incompatible Transfusion: ☐ Unintentional ☐ Intentional

☐ ABO System ..... Specify: _____

☐ Other System ..... Specify: _____

☐ Hemolytic Reaction: ☐ Acute ☐ Delayed } Cause: _____

☐ Delayed Serological Transfusion Reaction (new alloantibodies) ..... Specify: _____

☐ Bacterial Infection ☐ Viral Infection ☐ Other Infection

Specify type of infection: _____

Donor: ☐ Infected ☐ Uninfected ☐ Unknown

Specify type of infection: _____

1. RECIPIENT IDENTIFICATION

LAST NAME | FIRST NAME

HEALTH CARD NUMBER | HOSPITAL CARD NUMBER

Date of Birth: Day | Month | Year

Sex: ☐ Male ☐ Other ☐ Female ☐ Unknown

7. RESULTS OF INVESTIGATION & CONCLUSION (CONTINUED)

☐ TACO

*Please see reverse for definitions.

☐ TAD*

☐ TRALI* ..... Time to Recovery (hrs)_____

☐ Possible TRALI* ..... Time to Recovery (hrs)_____

→ Risk Factors:

☐ Hypotensive Reaction

→ ☐ ACE Inhibitors

☐ PTP

☐ TA-GVHD

☐ Hemochromatosis

☐ Aseptic Meningitis

☐ IVIg headache

☐ Unknown

☐ Other Results of Investigation

→ Specify:

Relationship of Adverse Event to Transfusion: *Please see reverse for definitions.* ☐ Definite ☐ Probable ☐ Possible ☐ Doubtful ☐ Ruled Out ☐ Not Determined

Severity of Adverse Event: *Please see reverse for definitions.*

☐ Grade 1 (Non-Severe)

☐ Grade 2 (Severe)

☐ Grade 3 (Life-threatening)

☐ Grade 4 (Death) ..... → Describe the circumstances of death:

☐ Not Determined

Outcome of Adverse Event: *Please see reverse for definitions.*

☐ Death ..... → Relationship of transfusion to recipient's death: ☐ Definite ☐ Doubtful ☐ Probable ☐ Ruled Out ☐ Possible ☐ Not Determined

☐ Major or Long-Term Sequelae

☐ Minor or No Sequelae

☐ Not Determined

Hospital Procedure Involved: Describe: | Action:

Equipment/Supplies Involved: Describe: (include brand names/lot/model numbers) | Action:

Medical Follow-up: Treatment or Preventative Measures:

Supplier/Manufacturer Notified: ☐ Yes ..... Name of person contacted: _____ Date & Time: Day | Month | Year | Time (hh:mm)

☐ No

Status of Investigation: ☐ In progress ☐ Concluded ☐ Cannot be conducted ..... Reason: _____

8. COMMENTS

Reporting Physician or Designate: Last Name | First Name | Signature:

Telephone Number: ( ) Ext | Date & Time: Day | Month | Year | Time (hh:mm)

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

CBS Medical Director: Last Name | First Name | Signature:

Telephone Number: ( ) Ext | 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

ICU **Intensive Care Unit**
All intensive care units including i.e. neonatal, special care nursery, neuro, medical, burn unit

ER **Emergency**
Emergency and/or Trauma areas

MSW **Medical/Surgical Ward**
All inpatient care areas within a facility i.e. medical ward, surgical, hematology

OB **Obstetrics**
Obstetrics including labour and delivery, case room and birth centre

OR **Operating Room**
Operating room including day surgery

REC **Recovery Room**
Recovery Room including post anesthesia recovery

CHR **Chronic Care**
Chronic Care refers to long term care facilities/units

OP **Outpatient Clinic**
Outpatient refers to ambulatory care areas, medical day units, essentially where outpatients would come to receive a transfusion during daylight working hours

4. CLINICAL SIGNS AND LABORATORY RESULTS

Hospital Sample Collection to be sent to blood supplier:

Call your local blood 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

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
      - PaO_2 / FiO_2 300 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
      - PaO_2 / FiO_2 300 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

7. RESULTS OF INVESTIGATION & CONCLUSION (CONTINUED)

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 was proven by investigation to have been caused by transfusion.

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) and 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.
- Contamination of the blood sample or laboratory contamination is not suspected.
- 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.