CANADIAN TRANSFUSION ADVERSE EVENT REPORTING FORM

Created by: _____ (name) on _____ (date (ddmmmyyyy)) Last modified by: _____ (name) on _____ (date (ddmmmyyyy)) Record closed ☐ Case ID: _____

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

☐ ADVERSE REACTION **(Complete all sections)**

FACILITY IDENTIFICATION

NAME OF FACILITY | TELEPHONE NUMBER ( ) | EXT

ADDRESS OF FACILITY

STREET # | NAME | TYPE | PO BOX

CITY | PROVINCE | POSTAL CODE

HOSPITAL CODE

1. RECIPIENT IDENTIFICATION

LAST NAME | FIRST NAME

HEALTH CARD NUMBER | HOSPITAL CARD NUMBER

ADDRESS OF RECIPIENT

STREET # | NAME | TYPE | APT # | PO BOX

CITY | PROVINCE | POSTAL CODE

HOME TELEPHONE ( ) | WORK TELEPHONE ( ) | EXT

Date of Birth: Day | Month | Year | Postal Code:

Sex: ☐ Male ☐ Female ☐ Other ☐ Not Given ☐ Unknown

2. CLINICAL HISTORY

Pregnancies/Miscarriages ☐ Yes <3 mo. ☐ Yes >3 mo. ☐ No ☐ Unknown

Transfusions ☐ Yes <3 mo. ☐ Yes >3 mo. ☐ No ☐ Unknown

Principal diagnosis: _____

General diagnosis: _____

Immune-Compromised ☐ Yes ☐ No ☐ Unknown

Describe: _____

Blood Group: ABO _____ Rh _____

☐ Other Describe: _____

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

Date/Time/Place Occurred | Day | Month | Year | Time (hh:mm) | Place: | Date/Time Reported | Day | Month | Year | Time (hh:mm)

3a. Incident Information

☐ Patient Identification Incident Specify: _____

☐ Product Related Incident Specify: _____

☐ Other Incident Specify: _____

☐ Product Tranfused

3b. Use of equipment and premedication

Filter	☐ Used	☐ Equip. Problem	Blood warmer	☐ Used	☐ Equip. Problem	Premedication	☐ No ☐ Yes
Pump	☐ Used	☐ Equip. Problem	Reinfusion device	☐ Used	☐ Equip. Problem	Specify drug/dose/route:	
Pressure device	☐ Used	☐ Equip. Problem	Other	☐ Describe			

3c. Report of possible transfusion related blood-borne infection

☐ Viral Specify: _____

☐ Bacterial, specify genus/species: _____ Result of gram stain: _____

☐ Other Specify: _____

4. CLINICAL SIGNS AND LABORATORY RESULTS

☐ None			☐ Oliguria	☐ Tachycardia	☐ Other skin rash		
☐ Pulse	P. before:	P. after:	☐ Diffuse Hemorrhage	☐ Chills / rigors	☐ Pain, specify:		
☐ Fever	T. before:	T. after:	☐ Urticaria	☐ Shortness of breath	☐ Hemoglobinuria		
☐ Hypotension	BP before:	BP after:	☐ Nausea / vomiting	☐ Shock	☐ Other, specify:		
☐ Hypertension	BP before:	BP after:	☐ Jaundice	☐ Death			

Abnormal Laboratory Results:

Abnormal Laboratory Tests: _____

Results: _____

Date specimen taken: Day | Month | Year

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

Bacterial Infection:

Blood Culture Recipient: Date & Time Taken: Day | Month | Year | Time (hh:mm) # of Neg. # of Pos.

Organism Identified (genus/species): _____

Blood Culture of Product: Date & Time Taken: Day | Month | Year | Time (hh:mm) # of Neg. # of Pos.

Organism Identified (genus/species): _____

Lot #: _____ Unit #: _____

5. SUSPECT PRODUCTS

Transfused blood product									Amount administered					Transfusion Started Date / Hour (ddmmmyyyy/hh:mm)		Transfusion Finished Date / Hour (ddmmmyyyy/hh:mm)	
Product code/name	Product modification: Hospital	Product modification: Supplier	Group of unit: ABO	Group of unit: Rh	Group of unit: N/A	Blood centre code	Unit no. or Lot no.	Expiry date (ddmmmyyyy)	Volume: ml	Fraction: 1/4	Fraction: 1/2	Fraction: 3/4	Fraction: 4/4				

Comments:

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CITY | PROVINCE | POSTAL CODE

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Date of Birth: Day | Month | Year — Postal Code:

Sex: ☐ Male ☐ Female ☐ Other ☐ Not Given ☐ Unknown

6. MEASURES TAKEN

☐ None ☐ Antihistamines ☐ Antibiotics ☐ Transfusion Stopped ☐ Steroids ☐ Antipyretics ☐ Supplementary O_2 ☐ Vasopressors ☐ Analgesics ☐ ICU Required ☐ Diuretics ☐ Product Culture ☐ Blood Culture ☐ Other, Specify: _____

Name (print) | ☐ Physician ☐ Transfusion Safety Officer ☐ Technologist ☐ Other, specify: _____

Signature: | Telephone number ( ) EXT | Date: Day | Month | Year

7. RESULTS OF INVESTIGATION & CONCLUSION

Allergic Reaction: ☐ Minor ☐ Severe/Anaphylactic/Anaphylactoid Signs & Symptoms: _____ ☐ Febrile Non-Hemolytic Reaction

Incompatibility: Pre-existing incompatibility: ☐ ABO Specify: _____ ☐ Other Specify: _____ ☐ New Alloantibodies: Specify: _____

Hemolytic Reaction: ☐ Acute ☐ Delayed

☐ Viral Infection	Specify: _____	Donor:	☐ Infected	☐ Uninfected	☐ Unknown
☐ Bacterial Infection	Specify genus/species: _____	Donor:	☐ Infected	☐ Uninfected	☐ Unknown
☐ Other Infection	Specify: _____	Donor:	☐ Infected	☐ Uninfected	☐ Unknown

☐ TA-GVHD ☐ TRALI ☐ Hemochromatosis ☐ Circulatory Overload ☐ Post Transfusion Purpura ☐ Hypotensive Reaction ☐ Aseptic Meningitis ☐ Unknown ☐ Other, specify: _____

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 Describe the circumstances of death: _____		
Outcome of Adverse Event:	☐ Death Relationship of transfusion to recipient's death: ☐ Definite ☐ Probable ☐ Possible ☐ Doubtful ☐ Ruled Out ☐ Not Determined ☐ Major or Long-Term Sequelae ☐ Minor or No Sequelae ☐ Not Determined		
Hospital Procedure Involved:	Describe:	Action:	
Equipment/Supplies:	Describe: (include brand names/lot/model numbers)	Action:	
Medical Follow-up:	Treatment or Preventative Measures	Action:	
Supplier/Manufacturer Notified:	☐ Yes ☐ No Name of Person Contacted: _____	Date & Time: Day / Month / Year / Time (hh:mm)	
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)