Trillium Gift of Life Network

TRILLIUM GIFT OF LIFE NETWORK
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CTO # 100062

SUSPECTED ERROR / ACCIDENT OR SERIOUS ADVERSE REACTION REPORT

Re: TGLN DONOR ID #: _____ Reportable by TGLN to Health Canada Yes: ☐ No: ☐ Unknown ☐

REPORT FROM:

TGLN as ☐ Source Establishment (Ontario Donor) ☐ Establishment (Out-of-Province Donor) ☐ Importer (Out-of-Country Donor)

Reported By: _____ (Name of Person completing this form) Fax Number: _____ (Fax # of reporting person) Date: _____ (Date form completed) Time: _____ (Time form completed)

REPORT TO:

Organ/Tissue/ Composite Tissue Description (write each organ/tissue/composite tissue on a separate line)	**Recipient ID Number** (if available)	**Name of Establishment** (Name of all programs that received organs or tissues from donor)	**Type of Establishment** (Organ Procurement Organization - OPO Transplant Program – TP Tissue Bank - TB)	**Contact Person** (Identify who this form is being sent to)	**Fax Number/Email** (Document fax #/Email for contact person)

SUSPECTED:

☐ Error (E) (A deviation from the Clinical Process Instruction (CPI) or applicable laws that could adversely affect the safety of a transplant recipient, or the safety, efficacy or quality of tissues, organs, or composite tissues.)

☐ Accident (A) (An unexpected event that is not attributable to a deviation from the CPI or applicable laws and that could adversely affect the safety of a transplant recipient, or the safety, efficacy or quality of tissues, organs, or composite tissues.)

☐ Adverse Reaction (AR) (An undesirable response in a tissue, organ, or composite tissue recipient, including transmission of disease or disease agent, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, is life-threatening or results in death.)

Name of suspected transmissible disease or disease agent (Provide any information if known, or state "unknown"): _____

Request for quarantine (If organ or tissue has already been released, select N/A.): ☐ Yes ☐ No ☐ N/A

Description of E/A or AR (Describe the occurrence that led to E/A or AR): _____

_____

Reason for belief that the safety of the tissues/organs/composite tissue may have been compromised and an explanation of how (if known) (Explain why an adverse reaction may result from the suspected E/A or AR): _____

_____

If TGLN was the Source Establishment:

All implicated tissues, organs and composite tissue are required to be quarantined immediately until further notice from TGLN establishment. All other specified corrective actions below from TGLN must be taken.

Description of Corrective Actions Required (If follow-up actions are required by program with organs not transplanted yet, please state. Otherwise select N/A.)

_____

_____ ☐ N/A

Additional Comments (Any additional comments or information that does not fit into any other field on this form) _____

_____

<u>Please attach all relevant documentation onto this form.</u>

All establishments are required to cooperate by providing information for the case investigation.

Fax one copy to relevant Organ Procurement Organization/Transplant Program/Tissue Bank.
A second copy remains in the TGLN Donor Chart File and a third copy of this report and any fax transmittal confirmation sheets is provided to the Quality Department (either as a photocopy or PDF)