Ontario
Trillium Gift of Life Network

Clinical Process Instruction Manual

Transplant Program – Suspected Donor Related Adverse Reaction Process Instruction

Policy:

Trillium Gift of Life Network (TGLN) as the source establishment for deceased organ and composite tissue donors, is required to report adverse reactions which have the possibility of being deceased donor related.

An adverse reaction is defined as 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.

Only unexpected serious adverse reactions require Health Canada notification. As such, in cases of known risk (i.e., exceptional distribution), a serious adverse reaction does not need to be reported to Health Canada.

If the reaction is both serious and unexpected, TGLN will ensure it is appropriately reported to Health Canada (Canada Vigilance) and relevant establishments (transplant programs, tissue banks, organ procurement organizations).

Process:

1. Transplant program identifies a recipient who is experiencing an adverse event which may be donor related.

2. Transplant Program completes the *Transplant Program – Suspected Donor Related Adverse Reaction Report* and submits it to TGLN's Quality Department. See Exhibit 1.

3. TGLN's Quality Director or designate reviews the form and follows-up with the Transplant Program within two business days of receiving the form to determine if the observed adverse reaction is reportable to Health Canada.

4. If it is determined that this is not a reportable adverse reaction (or that no adverse reaction has occurred), then TGLN's Quality Director informs the Transplant Program that the adverse reaction is not reportable and provides the rationale for this decision.

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5. If it is determined that this is a reportable adverse reaction, TGLN carries out the activities described in *CPI-7-701 Unexpected Serious Adverse Reaction Process Instruction*.

Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Transplant Program – Suspected Donor Related Adverse Reaction Report	CSF-9-219	Quality Assurance Department	Quality Assurance Department	16 years

References:

- Safety of Human Cells, Tissues and Organs for Transplantation Regulations

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Exhibit 1: Sample Transplant Program – Suspected Donor Related Adverse Reaction Report

Trillium Gift of Life Network

CSF-9-219

TRILLIUM GIFT OF LIFE NETWORK
483 Bay Street South Tower, 4th Floor Toronto, Ontario M5G 2C9
Telephone (24/7): 1.877.363.8456 Facsimile: 1.866.557.6100
CTO # 100062

TRANSPLANT PROGRAM – SUSPECTED DONOR RELATED ADVERSE REACTION REPORT

Date: _____

In the event an adverse reaction occurs in your transplant recipient, which possibly could be attributed to the deceased donor, please complete this form and return it to TGLN.

Rationale: TGLN as the source establishment is required to report adverse reactions which have the possibility of being deceased donor related. By reporting these adverse reactions to TGLN, we will be able to follow-up with other transplant programs to determine if the adverse reaction has occurred in another recipient or prevent it from occurring if it is donor related.

An adverse reaction is defined as 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.

Step 1: Reporter Information

Name of Transplant Program: _____

Reporter's Name: _____

Reporter's Phone Number/Email Address: _____

Reporter's Qualification: ☐ Physician ☐ Nurse ☐ Other (specify): _____

Step 2: Identification of a reportable suspected adverse reactions (check all that apply)

☐ Death:_____(YYYY-MM-DD)
☐ Life-threatening Condition
☐ Cause/Prolonged hospitalization
☐ Disabling/Incapacitating
☐ Congenital anomaly in donor organ
☐ Cancer (Type): _____
☐ Other medially important condition (specify): _____

Describe the reaction:

Step 3: Recipient Information

Recipient Name: _____

TGLN Recipient Number: _____

Step 4: Contact TGLN

Please email this form to TGLN Quality at Quality@giftoflife.on.ca. If there are any concerns, you will be contacted by the Quality Department within 2 business days.