Ontario Health
Trillium Gift of Life Network

Clinical Process Instruction Manual

Error/Accident Process Instruction

Policy:

As source establishment for deceased organ and composite tissue donors, Trillium Gift of Life Network (TGLN) is responsible for determining safety of organs and composite tissue for transplantation. TGLN ensures that the requirements of the *Safety of Human Cells, Tissues & Organs for Transplantation Regulations* are met by themselves and their partners. If a transplant program, tissue bank or another organ procurement organization (OPO) notifies TGLN that they have reasonable grounds to believe that the safety of tissue, organ or composite tissue has been compromised by an error or accident (E/A), TGLN will initiate an investigation. As defined by the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations*, an:

"Error" *means a deviation from the Clinical Process Instruction (CPI), or our partner's procedure, or applicable laws that could adversely affect the safety of a transplant recipient, or the safety, efficacy or quality of tissues or organs. (Example – TGLN forgets to perform a required screening test.)*

"Accident" *means an unexpected event that is not attributable to a deviation from the CPI, or our partner's procedure, or applicable laws and that could adversely affect the safety of a transplant recipient, or the safety, efficacy or quality of tissues or organs. (Example – TGLN performs a screening test which shows a negative result and another establishment performs the same test which turns out to be positive. Therefore, a confirmatory test needs to be done.)*

Upon notification of an incident, which is typically after organ or tissue distribution, TGLN will determine whether or not it is a reportable error or accident. If it is determined that an E/A has occurred, TGLN will notify all programs that accepted an organ or tissue from the donor and send a preliminary report to Health Canada within 24 hours. In addition, Health Canada will be provided with an update on the investigation on the 15th day, and every 15 days thereafter until the final report is submitted. If the 15 day update is due over the weekend or on a holiday, the update report will be submitted earlier (i.e. on the Friday) to ensure it meets the requirements. TGLN also provides all accepting transplant programs, tissue banks and Health Canada with the final investigation report, including final results (including root cause), final disposition of organ/tissue and corrective actions taken.

If TGLN believes that an investigation is not required, TGLN must notify the advising transplant program, tissue bank or OPO and provide justification. An investigation may not be required if there is reason to believe that it is not warranted.

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Process:

TGLN as Source Establishment

1. When TGLN receives an organ and/or composite tissue donor referral from an Ontario hospital, TGLN is considered to be "the source establishment" and the hospital/ transplant program is considered to be an "establishment".

Initial Error/Accident Reporting

2. When TGLN is advised of an error/accident after organ, tissue, and composite tissue distribution, the Clinical Services Coordinator (CSC) performs the following tasks:

    2.1 Obtains the TGLN identification number of the donor.

    2.2 Reviews the corresponding donor chart to determine the accepting program and recipient identification number, if available, for all organs, tissues and composite tissue accepted.

    2.3 Immediately verbally notifies all accepting transplant programs, OPOs and tissue banks and notifies all pertinent establishments that a suspected error/ accident has been detected in the donor processing. The CSC provides an explanation of how the organ(s)/tissue(s)/composite tissue(s) may have been compromised, if known. The CSC documents these conversations in the donor chart's clinical notes, ,

    2.4 If organ(s) have not yet been transplanted, the CSC ensures that any implicated organ(s) or composite tissue(s) in TGLN's possession are quarantined in the designated surgical recovery storage room.

    2.5 The CSC completes the *Suspected Errors/ Accidents or Serious Adverse Reaction Report* with the error/ accident situation. See Exhibit 2 for a copy of the report. The CSC sends the report to all relevant organ and tissue establishments, such as:

    - source establishment(s) for tissues, to which a donor referral was made.
    - any establishment which was distributed implicated organ(s)/composite tissue(s).

    The CSC documents the programs that were sent the report in the clinical notes.

This is filed in the donor chart and a copy of the *Suspected Error/Accident or Serious Adverse Reaction Report*, and fax transmittals (or equivalent) are forwarded to the Quality Department.

2.6 The CSC notifies the Director Quality or designate during business hours (9:00 am to 5:00 pm). If not during business hours, the CSC emails the Director Quality or designate.

Error/Accident Preliminary Investigation Reporting

3. Director Quality or designate is responsible for initiating an investigation into the suspected error/ accident.

4. If notified during business hours, the Director Quality or designate initiates the investigation immediately. If notified outside of business hours, the Director Quality or designate will initiate the investigation on the next business day.

5. The Director Quality or designate, completes the *Human Cells, Tissues and Organs for Transplantation – Error or Accident Preliminary Investigation Report*. See Exhibit 3 for a copy of the report. The Director Quality or designate sends the report to Health Canada within 24 hours of initiating the investigation if it is determined that the reported suspected error/accident is legitimate.

6. If the Quality Director or designate determine that no error/accident has occurred, all establishments that received the *Suspected Error/Accident or Serious Adverse Reaction Report* are notified in writing that no investigation is required and the reason(s) why this is the case.

Error/Accident Follow-up

7. Director Quality or designate provides an update on the error/ accident investigation to Health Canada after 15 days, and every 15 days thereafter until completion of the investigation.

8. The quality department will request a recipient update from the transplant program(s) as needed for the follow up reports in collaboration with the Clinical Specialist Organ or their designate.

9. Director Quality or designate submits a final report upon case closure to Health Canada, including the results, root cause if known, final disposition of tissue(s)/organ(s)/composite tissue(s) and any corrective actions taken.

9. The final report is provided to all establishments that were notified of the error/accident after notification of case closure from Health Canada is received but before the next scheduled Health Canada Inspection.

10. For all reports sent to relevant organ and tissue establishments and Health Canada, copies of these report(s), quality checklist (if used) and the fax transmittal confirmation sheets (or equivalent) will be filed by the Quality Department.

TGLN as Establishment

11. When TGLN accepts an organ(s)/composite tissue(s) from an OPO from another province or recovers tissue for a tissue bank. TGLN is considered to be “an establishment” with the provincial OPO or accepting tissue bank as the “source establishment”.

12. When TGLN is advised of an error/accident from the source establishment, the CSC works with the Director Quality or designate to perform the following tasks:

    12.1 Obtains the donor identification codes of the transplanted organ(s)/composite tissue(s).

    12.2 Ensures that any implicated organs/composite tissue in TGLN’s possession are quarantined in the designated surgical recovery storage room.

    12.3 Telephones all accepting Ontario Transplant Programs and advises that an error/accident has been detected in the donor processing.

    12.4 Forwards a copy of the Error/Accident Report from the source establishment to all establishments to which TGLN distributed the implicated organ(s)/composite tissue(s), as well as to the Director Quality or designate.

13. When TGLN is advised of an error/accident from another establishment, to which organ(s)/composite tissue(s) were distributed, the CSC works with the Director Quality or designate to perform the following tasks:

    13.1 Obtains the donor identification codes of the transplanted organ(s)/composite tissue(s).

    13.2 Ensures that any implicated organ(s)/composite tissue(s) in TGLN’s possession are quarantined, in the designated surgical recovery storage room.

13.3 Telephones all accepting Ontario Transplant Programs and advises that an error/accident has been detected in the donor processing.

13.4 Ensures that the source establishment is provided with a copy of a *Suspected Errors/ Accidents or Serious Adverse Reaction Report* if TGLN documented the error/accident or a copy of an Error/ Accident Report if the establishment which identified the error/accident provided one.

13.5 Provides the source establishment with a listing of all of the establishments to which TGLN distributed the organs/composite tissues.

TGLN as Importer

14. When TGLN accepts an organ(s)/composite tissue(s) from an OPO from another country, TGLN is considered to be “an importer” with the international OPO as the “source establishment”.

15. When TGLN is advised of an error/accident from the source establishment, the CSC works with the Director Quality or designate to perform the following tasks:

15.1 Obtains the donor identification codes of the transplanted organ(s)/composite tissue(s).

15.2 Ensures that any implicated organ(s)/composite tissue(s) in TGLN’s possession are quarantined in the designated surgical recovery storage room.

15.3 Telephones all accepting Ontario Transplant Programs and advises that an E/A has been detected in the donor processing.

15.4 Forwards a copy of the Error/ Accident Report from the source establishment to all establishments to which TGLN distributed the implicated organ(s), as well as to the Director Quality or designate.

16. When TGLN is advised of an error/accident from another establishment, to which organ(s)/composite tissue(s) were distributed, the CSC works with the Director Quality or designate to perform the following tasks:

16.1 Obtains the donor identification codes of the transplanted organ(s)/composite tissue(s).

16.2 Ensures that any implicated organ(s)/composite tissue(s) in TGLN's possession are quarantined, in the designated surgical recovery storage room.

16.3 Telephones all accepting Ontario Transplant Programs and advises that an error/accident has been detected in the donor processing.

16.4 Ensures that the source establishment is provided with a copy of a *Suspected Errors/Accidents or Serious Adverse Reaction Report* if TGLN documented the error/accident reaction or a copy of an Errors/Accidents Report if the establishment which identified the error/accident provided one.

Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Suspected Error/Accident or Serious Adverse Reaction Report	CSF-9-90	Quality Assurance Department	Quality Assurance Department	16 years
Human Cells, Tissues and Organs for Transplantation – Error or Accident Preliminary Investigation Report	CSF-9-88	Quality Assurance Department	Quality Assurance Department	16 years
Quality Donor Chart Checklist	CSF-9-89	Quality Assurance Department	Quality Assurance Department	16 years

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References:

- Safety of Human Cells, Tissues and Organs for Transplantation Regulations
- Human Cells, Tissues and Organs for Transplantation – Error or Accident Preliminary Investigation Report

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Exhibit 1: Suspected Error/Accident or Serious Adverse Reaction Report

Trillium Gift of Life Network

CSF-9-90

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

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): _____

_____

Please attach all relevant documentation onto this form.
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)

September 29, 2021

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Exhibit 2: Human Cells, Tissues and Organs for Transplantation – Error or Accident Preliminary Investigation Report

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Health Canada Santé Canada

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Human Cells, Tissues and Organs for transplantation –
Error or Accident investigation reporting form (FRM-0172)

Suspected Errors or Accidents (E/A) identified after distribution of Cells, Tissues and Organs (CTO), that could lead to a serious adverse reaction involving the transmission of an infectious disease or disease agent, are to be reported to Health Canada. A preliminary report must be issued within 24 hours after the start of the investigation. An update (follow-up report) is required to be submitted within 15 calendar days after the start of the investigation and every 15 calendar days after, until the final report is submitted. A final report describing the results of the investigation, final disposition of implicated CTO, reason for disposition, and any corrective actions taken, must be submitted upon completion of the investigation. For further information, *refer to the Guidance Document for Cell, Tissue and Organ Establishments* and the Safety of Human Cells, Tissues and Organs for Transplantation Regulations.

A) Information related to the source establishment reporting to Health Canada

A.1	Type of report: ☐ Preliminary ☐ Follow-up ☐ Final	
A.2	Date of this report: (yyyy/mm/dd)	
A.3	Establishment's E/A reference number (optional):	
A.4	Name of the source establishment:	
A.5	Name/title of the person reporting:	
A.6	Establishment registration number:	
A.7	Address of source establishment (street, city, province/state, postal code):	
A.8	Phone number:	A.9: Fax number:
A.10	Contact person:	

Pub: 200253

Canada