Ontario
Trillium Gift of Life Network

Quality Process Instruction Manual

Incident Process Instruction

1.0 Purpose:

To describe the process for investigating and resolving organ-related incidents.

2.0 Scope:

This process instruction applies to

- Trillium Gift of Life Network (TGLN) – Organ Group

3.0 Responsibilities:

Director Quality is responsible for:

- ensuring adherence to the Incident Process Instruction by all employees
- performing a preliminary investigation for all incidents
- assigning the incident to the appropriate employee(s) and ensuring that the process is conducted
- ensuring that the implemented, recommended action plans are verified and communicated to the affected employee(s)

Quality Department Investigators are responsible for:

- performing a detailed investigation
- developing recommendations in collaboration with the affected stakeholders
- ensuring that the implemented, recommended action plans are verified and communicated to the affected employee(s)

Managers/Directors are responsible for:

- reporting incidents, whenever one is identified
- reviewing incident submissions from employees
- implementing any proposed recommendations from the investigation, when requested

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Employees are responsible for:

- reporting incidents to management when an incident is identified
- assisting in providing information to an investigation, when requested

4.0 Process:

4.1. Incidents are a form of minor nonconformances which might occur either internal or external to TGLN. See the *Nonconformance Procedure, QSP-13-1* for further details.

4.2. Incidents are defined as deviations/variances from the pre-established organ donation, and recovery processes that either have caused or could cause a near-miss and/or an adverse outcome that needs to be resolved. The scope of the incidents under review include all donor assessment-related and recovery-related activities performed by TGLN and its partners, from donor referral to organ transplant. More specifically, incidents are caused by one or more of the following reasons:

- A Health Canada – related nonconformance to a pre-established donation or recovery process that potentially could result in a safety risk to the recipient
- The loss of a potential donor or suitable organ due to system delays or errors caused by staff or external stakeholders during the donation and recovery processes

4.3. The Incident Reporting process is outlined below:

4.3.1 Clinical staff, who have editing access to the electronic donor management system, can report an incident by recording a variance note in iTransplant. The Director Quality and management of the clinical department will review the variance note to assess if the reported incident should be investigated further. If an investigation is warranted, a request will be made for the management of the clinical department to complete and submit an *Incident Intake Sheet, QSF-14-6*, to Quality. See Exhibit 2

4.3.2 Employees, with no access to iTransplant, can report an incident to his/her manager. The manager will complete and submit an *Incident Intake Sheet to Quality.*

4.3.2. If a related incident investigation has previously been conducted by a department other than Quality, the report will be forwarded to the Director Quality for review. The Director Quality and the management of the clinical department will review to

assess if the reported incident should be investigated further. If a new investigation is warranted, a request will be made for management of the clinical department to complete and submit an Intake Sheet to Quality.

4.3.3. External stakeholders can report incidents to Quality. The Director Quality and management of the clinical department will review to assess if the reported incident should be investigated further. If an investigation is required, a request will be made for the management of the clinical department complete and submit an Intake Sheet to Quality.

4.4. The Director Quality conducts a preliminary investigation. The length of time for a preliminary investigation would be approximately one business week. Delays due to pertinent stakeholder or information availability may impact this timing. Depending on the preliminary investigation outcome, some of the alternative next steps include:

- assigning the investigation to a Quality department employee.
- responding to the incident initiator that the investigation process will not yield sufficient benefit to warrant continuing on with the investigation.

4.5. Incidents that are investigated, are logged on QSF-14-9. See Exhibit 5.

4.6. If the incident investigation proceeds, the pertinent investigation details will be gathered by the assigned investigator that the Director Quality identifies.

4.7. As needed, a *Containment Plan, QSF-14-3* is developed and implemented immediately by the investigator and the pertinent departmental management. See Exhibit 3.

4.8. Data gathering and employee interviews are conducted to learn the specifics of the incident.

4.9. If information is required from an external stakeholder, a *Stakeholder Follow-Up* form, *QSF-14-5* may be sent to those individuals by the assigned investigator. See Exhibit 4.

4.10. A draft incident report is developed after the information has been gathered. See Exhibit 1.

4.11. If the case is considered to be complex or the appropriate recommendations are subjective, a draft report without any documented recommendations, is sent to the appropriate internal staff to solicit their input. After incorporating their feedback, the Quality Department Investigator calls a meeting to identify the pertinent

recommendations needed to go forward. A documented copy of the revised report is again sent out to the pertinent stakeholders for their feedback. If external stakeholders are implicated, the Quality Department Investigator will either forward the draft report to the stakeholder's quality representative or conduct a meeting with the relevant stakeholder.

4.12. A final investigation report is developed and sent out by the Director Quality or his designate, to the appropriate staff and external stakeholders.

4.13. The recommendations are implemented by the affected stakeholders and they are asked to submit evidence of successful resolution to Quality, by the timing agreed with relevant staff.

5.0 Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Incident Report	QSF-14-8	Director Quality	Quality Assurance Department	16 years
Incident Intake Sheet	QSF-14-6	Director Quality	Quality Assurance Department	16 years
Containment Plan Form	QSF-14-3	Director Quality	Quality Assurance Department	16 years
Stakeholder Follow-Up Form	QSF-14-5	Director Quality	Quality Assurance Department	16 years

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Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Incident Report Directory	QSF-14-9	Director Quality	Quality Assurance Department	16 years

6.0 References:

- *Nonconformance Procedure, QSP-13-1*
- *Corrective and Preventive Action Procedure, QSP-14-1*
- *Critical Incident Process Instruction, QPI-14-1*

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Exhibit 1: Sample Incident Reports

QSF-14-8

INCIDENT REPORT

IR #: _____ Date Logged: _____

Report Initiator: _____ TGLN #: _____

☐ Intake Sheet ☐ Variance Note ☐ Investigation Report

☐ Other _____

Problem Description:

Incident Investigator: Estimated Due Date:

Findings

Conclusions

Recommendations for Consideration

November 29, 2018

Trillium Gift of Life Network

Case Summary: Incident
TGLN Reference#
Date:

Issue

Background

Incident Summary

Case Review Findings

Summary:

Conclusions:

Recommendations

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Exhibit 2: Sample Incident Intake Sheet

QSF-14-6

INCIDENT INTAKE SHEET INCIDENT #: INC - YYYY -

REQUESTOR

INITIATED BY: _____ DATE LOGGED: _____

REVIEWED BY: _____ TGLN #: _____

DESCRIPTION of Incident

TYPE OF INCIDENT	STAFF INVOLVED	STAKEHOLDERS INVOLVED
☐ Potential Critical Incident	1	1
☐ Potential Incident	2	2
☐ Complaint	3	3
	4	4
	5	5

CLINICAL CHART NOTES (IF APPLICABLE)

DATE/TIME	EVENT

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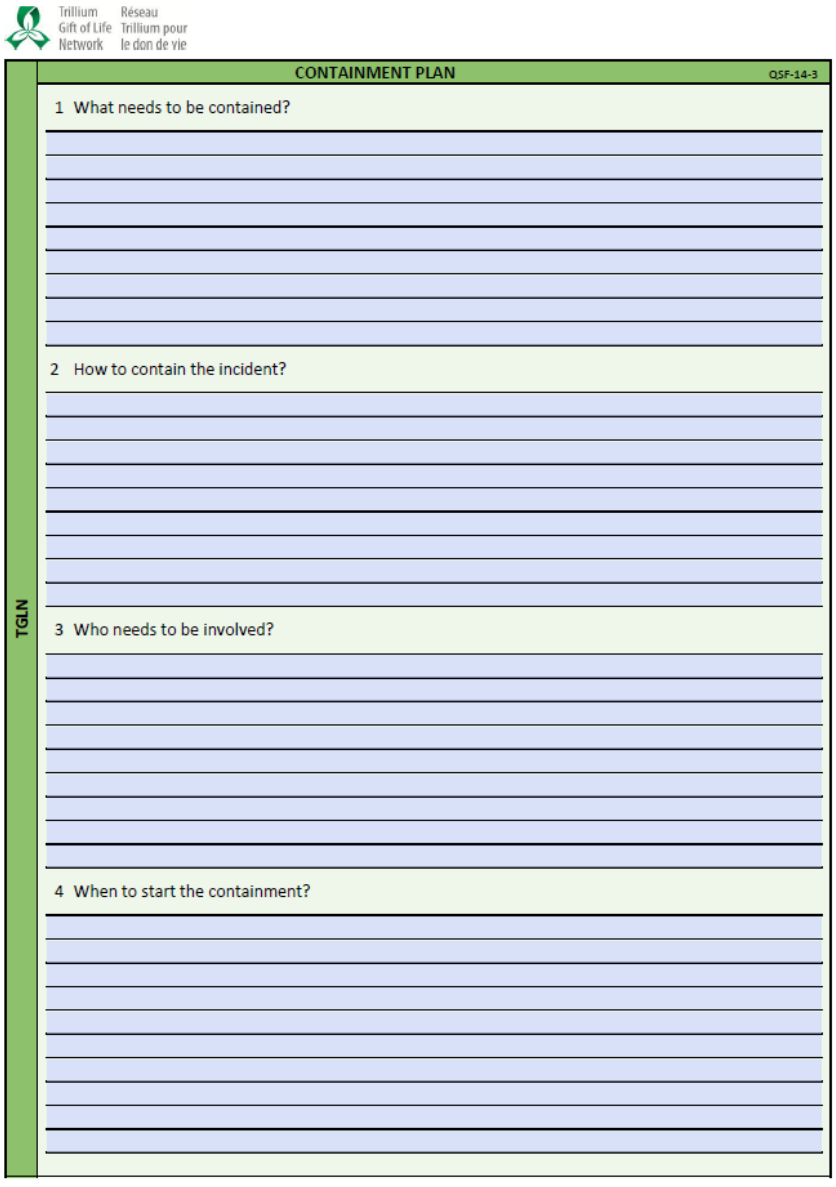
Exhibit 3: Sample Containment Plan



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TGLN

CONTAINMENT PLAN QSF-14-3

1 What needs to be contained?

2 How to contain the incident?

3 Who needs to be involved?

4 When to start the containment?

August 31, 2016

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Exhibit 4: Sample Stakeholder Follow-Up form

STAKEHOLDER

STAKEHOLDER FOLLOW-UP QSF-14-5

NAME OF STAKEHOLDER:

ORGANIZATION NAME:

DATE OF FOLLOW-UP:

FOLLOW-UP QUESTIONS:

1

2

3

4

5

6

7

8

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Exhibit 5: Incident Report Directory

QSF-14-9

INCIDENT REPORT DIRECTORY

IR #	Date Logged	Problem Description	Reported By	Incident Solution	Approved By	Incident Close-out Date