

Clinical Process Instruction Manual

Ontario Tissue Exclusive Referral Donation Process Instruction

Policy:

Designated facilities* in the province of Ontario are required by the *Gift of Life Act* and associated regulations to notify Trillium Gift of Life Network (TGLN) within one hour of all deaths. This notification may occur before death if death is imminent. TGLN personnel in the Provincial Resource Centre (PRC) includes Tissue Coordinator (TC), Clinical Services Coordinator (CSC)/Referral Triage Coordinator (RTC) who will manage the referrals to determine if the patient is eligible for donation. Upon receipt of a tissue referral, TGLN determines if the referred patient has registered their consent decision via the Registered Persons Database (RPDB). TGLN, along with the hospital and healthcare professionals (HCPs), will ensure that each potential donor and their family are provided with the option of tissue donation as a part of standard end-of-life care.

Tissue exclusive donation is considered when a patient is referred to TGLN after cardio-circulatory death has occurred.

Process:

1. HCPs – Registered Nurse (RN), Registered Practical Nurse (RPN), RN Extended Class (EC) or Doctorate of Medicine (MD) will call the PRC if a patient has died or if patient death is imminent by reason of injury or disease. Prior to making the call the HCP has been advised to have the *Routine Notification Worksheet* (see Exhibit 1) and patient chart readily available to facilitate the call.
2. The PRC TC will also register referrals from ‘other’ referring organizations and/or persons which include but are not limited to paramedic/EMT, funeral directors, MAID coordinators, Hospice facilities and primary care physicians. It is important to note that out-of-hospital referring organizations or persons often cannot provide recorded medical history, lab or diagnostic test results; the TC will nonetheless document the referral with any readily available information and proceed to next steps – additional information can be obtained from other sources (coroner, pathologist, NOK, family physician/specialist) should the referral proceed to consent & recovery.
3. If the HCP makes the donor referral to an Organ and Tissue Donation Coordinator (OTDC), the OTDC informs the HCP that the referral must be relayed directly to the PRC. The OTDC will provide the HCP with the PRC telephone number and the *Routine Notification Worksheet*.
3. Each referral shall be assigned a unique TGLN identification (ID) number to facilitate tracing of the case from referral to final disposition. This TGLN ID number will be assigned to every piece of documentation or specimen that is collected. The TGLN ID number is provided to the HCP and/or other referring organizations or persons, who are requested to record the number in the patient’s chart.

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4. The PRC coordinator collects and records patient demographics as required. This includes but is not limited to:
 - date and time of referral (automatically generated by iTransplant)
 - referring hospital, unit, telephone, fax; referring organization's name/address/telephone
 - name of caller and designation
 - name of patient (first, last)
 - patient date of birth
 - gender of patient
 - hospital record number, if applicable
 - OHIP number and version code
 - ventilation status
 - type of referral (organ, combined organ/tissue, tissue)
5. The PRC Coordinator asks scripted questions to identify donor potential. If the HCP and/or other referring organization/person indicates that the potential donor is intubated and being ventilated (either mechanically or manually with a Bag Valve Mask/Ambu-bag) or is on an external mode of ventilation (i.e. C-Pap or Bi-Pap), the CSC/ RTC will screen for organ donation potential, as per *Ontario Organ or Combined Organ and Tissue Donation Process Instruction, CPI-9-100*. TCs shall not enter the referral; TC must transfer the call immediately to an RTC/CSC.
6. If it is determined that the patient is not being ventilated, the PRC coordinator then documents the date and time of death, whether the death was witnessed and the cause of the death. If the death was witnessed or life-saving procedures have been attempted, a documented pronounced time of death is used as asystole. If the death was not witnessed, then asystole must be determined by the last time the potential donor was known to be alive.
7. If the patient exceeds age criteria, the patient is ruled out and the cause of death and the date and time of death are documented. The HCP or referring organization/person is informed that patient does not meet requirements for transplant. The patient is ruled out and the referring facility is provided with the TGLN ID number and asked to record the number on the patient chart. There is no requirement to report non-intensive Care Unit(ICU) or non-Emergency Department(ED) patients who are 80 years of age and older. All ICU and ED patients (includes medical/surgical intensive care unit (MSICU), critical care unit (CCU), cardiovascular intensive care unit (CVICU),

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pediatric intensive care unit (PICU), catheterization laboratory (cath lab)/resuscitation (resus), must be reported, irrespective of their age.

8. The TC asks the HCP or referring organization/person if the patient had and/or exhibited or there was a query of contraindicators (Absolute Exclusion Criteria) to tissue donation; if any, the patient is not eligible to donate. If there are no contraindicators, the TC continues the referral and collects as much medical information necessary to assess eligibility for tissue donation.
9. Once all readily available medical information is documented, the TC consults individual tissue banks Exclusion Criteria per *General Tissue Donation Criteria and Contraindicators Process Instruction, CPI-9-262*, and determines which tissue the patient is eligible to donate. If it is determined that the patient does not meet any of Tissue Bank's criteria, the HCP or referring organization/person is informed that the patient is not eligible for tissue donation for transplantation. The TC may further inform the HCP or referring organization/person that patient may still be eligible to donate tissue for research or teaching (R&T) purposes (if R&T tissue is needed).
10. If the patient is free from the absolute exclusion and Tissue Bank exclusion criteria, the TC informs the HCP or referring organization/person that the patient may be eligible to donate tissue for transplant.
11. For eligible patients, TC will ask the HCP if a coroner is involved. If a potential donor is deemed to be a Coroner's case, Trillium Gift of Life Network (TGLN) will not proceed with donation unless appropriate consent has been obtained as per *Coroner's Case Process Instruction, CPI-9-203*.
12. The ventilation status, cause of death, and date/time of death shall be documented on all cases (including cases that have been automatically ruled out). The PRC coordinator must also document the date and time of extubation, if applicable.
13. Complete the admission course, medical history and record the height and weight of the patient.
14. The TC will complete the remainder of the tissue donor screening information to determine which tissues the patient is potentially eligible to donate (as per steps 8 & 9), and confirm that no one has yet approached the family about donation. Record the next-of-kin (NOK) name(s), contact numbers, relationship to patient, and whether or not the NOK is on site or has left the hospital. TC must confirm that the NOK have been informed of the death. If the NOK have not been informed of the death, advise the HCP or the referring organization/person to contact the PRC once the

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NOK have been made aware of death. If referring organization/person does not call back within 1-2 hours, the TC shall contact the organization/person for a status update.

15. Once the assessment is complete and the patient is determined to be initially medically suitable, the TC will perform the tissue approach, if the NOK are nearby and willing to speak to TC .
16. Prior to approach, the TC shall obtain information from the HCP or referring organization/person on family dynamics and timing.
17. If the HCP indicates that the current timing is not suitable for tissue approach the TC shall evaluate the situation for the need to approach and will approach or set a plan with the HCP or referring organization/person to approach at a later set time. TCs shall document the NOK's contact name, phone number and the approach plan shall be documented in iTransplant Clinical Notes.
18. If the NOK did not come on-site or has already left the hospital/location of the deceased, attempt to approach shall take place within one hour after the initial referral call is complete using the contact numbers provided.
19. If NOK has expressed interest in donation, but the TC is unable to get in contact with the NOK after the first attempt, the TC will call the referring hospital (or coroner if involved) to determine if there is additional contact information.
20. *A Hold Body Form - Tissue Donation Consideration* is immediately faxed to the location listed in the Tissue Profile (if applicable). This applies to consented tissue donors and potential tissue donors in which the approach has not been completed. See Exhibit 2. In instances where the Tissue Profile states that a phone call is required to hold the body, no *Hold Body Form Tissue Donation Consideration* will be faxed.
21. If the TC is unable to take the initial referral, the PRC Coordinator obtains the HCP's or referring organization/person's telephone number and informs the caller that a TC will contact him/her shortly to obtain more information about donor suitability and approaching the NOK. If the caller is an HCP, the TC will advise HCP to keep the patient information (physical/electronic chart) available.
22. If the HCP or referring organization/person has already approached the family, document the outcome of the conversation and the name of the individual who performed the approach. The PRC coordinator will inform the HCP or referring organization/person that TGLN is responsible for approaching families for donation. If the NOK has declined donation, the reason for decline will

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be documented. When applicable (e.g. registered consent decision), TGLN will re-approach the NOK and document the interaction.

Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Hold Body Form Tissue Donation Consideration	CSF-9-4	PRC	PRC	16 years
Coroner Permission Form	CSF-9-7	PRC	PRC	16 years

References:

- *Ontario Organ or Combined Organ and Tissue Donation Process Instruction*, CPI-9-100
- *General Tissue Donation Criteria and Contraindications Process Instruction*, CPI-9-262
- Gift of Life Act, R.S.O 1990, c. H.20. Last amendment: 2021, c.4, Sched. 11, s. 39. Retrieved from: [Gift of Life Act, R.S.O. 1990, c. H.20 \(ontario.ca\)](http://www.ontario.ca).
- Standards for Tissue Banking, American Association of Tissue Banks, United States, 14th edition, 2017. D4.000.


Exhibit 1: Sample Routine Notification Worksheet Page 1

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Routine Notification Worksheet

Note: This worksheet does not include screening questions for patients who have requested Medical Assistance in Dying (MAID). Use the MAID: Pre-Provision Intake Form.

Place patient addressograph/sticker here or fill out questions 2-6 below.

Call Initiated By: _____ Signature: _____

Complete this form prior to calling TGLN and **have the patient's chart available.**


1. Unit Telephone #: _____ Unit Fax #: _____
2. Name of Patient: _____
3. Date of Birth: DD ____ MM ____ YYYY ____
4. Sex: Female Male Identifying Gender, if Different ____
5. Medical Record Number (i.e., Patient "J-Number" or "Sh-Number" etc.): _____
6. OHIP #: _____ Version Code: _____
7. Is the Patient Ventilated (Including BiPAP²/CPAP)?: No Yes If Yes, indicate if ETT, BiPAP², or CPAP
8. TOD: DD ____ MM ____ YYYY ____ HH:MM ____
9. Was the Death Witnessed?: Yes No If No, Last Time Seen Alive: _____
10. Clinical History: Note Any Conditions Listed to the Right
11. Suspected Cause of Death (e.g. CVA): _____ If Cancer, Type: _____
12. Mechanism of Death (e.g. MVC): _____
13. Date of Entry/Admission to Hospital: DD ____ MM ____ YYYY ____ HH:MM ____
14. Intubation Date & Time (if applicable): DD ____ MM ____ YYYY ____ HH:MM ____
15. Extubation Date & Time (if applicable): DD ____ MM ____ YYYY ____ HH:MM ____
16. Substitute Name: _____ Relationship: _____
Cell #: _____ Home #: _____ Other #: _____

TGLN may ask additional screening questions.

Complete the Next Steps Worksheet or have the chart available to answer questions such as: past medical history, brain stem reflexes, vital signs, medications, antibiotics in last 2 weeks, most recent lab values, temperature, cultures, chest x-ray, height, weight, family MD, coroner's case, IV fluid in last hour before TOD, or blood products in last 48h

TGLN Number: _____ Document as per hospital policy

Screening Outcome	
<p>ICU/ED Ventilated patients</p> <p style="font-size: small;">Prior to the withdrawal of life sustaining measures</p>	<p><input type="checkbox"/> Eligible for organ donation Thank you for not discussing donation with the family. TGLN will speak with the family at an appropriate time. Call TGLN back with any changes to the patient's condition or plan of care.</p> <p><input type="checkbox"/> May be eligible for tissue donation Call back within one hour of death. The screening for tissue donation must include your patient's medical information at the time of death.</p> <p><input type="checkbox"/> Not eligible for organ or tissue donation No call back required at time of death.</p>
<p>All Units</p> <p style="font-size: small;">Within one hour of asystole</p>	<p><input type="checkbox"/> Eligible for tissue donation Do not bring up the topic of donation with the family. A TGLN coordinator will discuss donation with the family over the phone. If the family is present, leading practice is to connect TGLN with the substitute before they leave the hospital. Suggested language to support the introduction of this conversation is available on the back of this page.</p> <p><input type="checkbox"/> Not eligible for tissue donation</p>



Ontario Health
Trillium Gift of Life Network

May 2021

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Exhibit 2: Hold Body Form Tissue Donation Consideration

CSF-9-4



Label/Addressograph

Patient Surname:
Patient First Name:
Est. Date/Time of Death:
Hospital ID/MRN #:
TGLN #:
Fax #: &

**Hold Body Form
Tissue Donation Consideration**

Please Call Trillium Gift of Life Network
PRIOR to release of body for Autopsy/Funeral Home

416-363-4438 or 1-877-363-8456 (Press 2)
Available 24hrs

For any questions, concerns, or family requests to release body please call the above number.

Holding the body ensures eligibility for tissue donation can be established and donation consent decisions can be accessed in the Ontario Health Insurance Plan (OHIP) Registered Persons Database before families of medically eligible patients are approached by TGLN about the opportunity to donate. This form does not indicate that tissue donation has occurred or will occur. This practice is consistent with the authority of TGLN in the Gift of Life Act to determine whether family be contacted in connection with the opportunity to donate.

TGLN Special Instructions:

Date and Time Sent:

-May 26, 2021

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