Clinical Process Instruction Manual

DCC Consent Process Instruction

Policy:

Ontario Health (Trillium Gift of Life Network [TGLN]) obtains consent prior to facilitating organ donation following Death Determination by Circulatory Criteria (DCC). The option of donation following DCC shall only be presented by an Ontario Health (TGLN) Coordinator after a healthcare team has advised that the patient or their substitute decision maker (SDM) (if the patient is incapable), as per the *Health Care Consent Act* (HCCA), has made a decision to withdraw consent for ongoing life-sustaining therapy or has accepted a recommendation for the withdrawal of life-sustaining measures (WLSM). Consent for donation after DCC may also be provided through a patient's advance directive.

Consent for donation following DCC differs from consent for donation following Death Determination by Neurologic Criteria (DNC), in that the optimal protocol for DCC includes pre-mortem interventions to optimize the outcome of organs to be recovered. These interventions are not therapeutic for the patient, and require a second, separate consent in addition to the general consent for organ and tissue donation.

The Specialist, Organ and Tissue Donation (SOTD) or Clinical Responder (CR) facilitates the discussion and obtains consent using the *Consent to Interventions for the Purpose of Organ Donation after Death Determination by Circulatory Criteria* (Exhibit 1). The SOTD/CR shall ensure that consent is properly documented. In some cases, the substitute as per the *Gift of Life Act,* and the SDM as per HCCA, are not the same individual. The SOTD/CR ensures that the appropriate legal authority in each case has provided consent.

Process:

1. Prior to presenting the option of donation following DCC to the patient, family/substitute(s), and/or SDM, the SOTD/CR ensures that the following items have been documented on the patient's chart:
   evidence of a discussion stating that withdrawal of life-sustaining measures (WLSM) is planned
   the MRP has documented that the patient, family/substitute(s), and/or SDM has agreed to WLSM
   - for patients requesting MAID, see CPI-9- 223 *Medical Assistance in Dying and Donation Process Instruction* (Note: Consent by a conscious, competent person [e.g., MAID] requires only *First-Person Consent to Donate Organs and/or Tissues* form to be completed [Exhibit 3]. This document encompasses all interventions.)

2. For patients who are incapable of giving consent by reason of injury or disease, the SOTD/CR will identify the appropriate substitute in accordance with the *Health Care Consent Act* (i.e., SDM) and the *Gift of Life Act.* (i.e., substitute) to complete consent and discuss the need for two separate consent forms:

a) *Consent to interventions for the purpose of Organ Donation after Death Determination by Circulatory Criteria* (Exhibit 1) is obtained for all pre-mortem assessments and interventions to optimize organs being recovered for the purposes of organ donation and will be signed by the patient's SDM in accordance with the *HCCA*.

b) *Consent to Donate Organs and/or Tissues* (Exhibit 2) is obtained for all post-mortem interventions to facilitate donation of organs and/or tissues and will be signed by the patient's substitute in accordance with the *Gift of Life Act*.

Note: In some cases, the substitute as per the *Gift of Life Act,* and the SDM as per *HCCA*, may not be the same individual. The SOTD/CR will ensure that the appropriate legal authority in each case has provided consent and that consent is properly documented.

3. If there is no SDM and the patient has a registered consent decision, the *Consent to Interventions for the Purpose of Organ Donation following Death Determination by Circulatory Criteria* is not required if the following circumstances are met.
   - The patient has a registered consent decision; AND
   - There are no available substitute decision-makers under the *Health Care Consent Act;* AND
   - The most responsible physician (MRP) has proposed a plan for withdrawal of life-sustaining measures to the Public Guardian and Trustee (PGT); AND
   - The PGT has provided consent for the withdrawal of life-sustaining measures (WLSM) plan; AND
   - The WLSM plan enables donation to proceed; AND
   - There are no available substitutes under the *Gift of Life Act;* AND
   - The MRP's medical opinion indicates organ testing or administration of heparin is not "treatment" under the *Health Care Consent Act* AND the interventions will not hasten death.

When applicable, consent for organ and tissue donation may also be provided through a patient's advance directive and obtain as indicated in Step 2.

4. If the patient, family/substitute(s), and/or SDM would like to proceed with donation following DCC, the SOTD/CR will provide detailed information about the donation process and answer any questions they may have.

5. The SOTD/CR explains that a detailed donor medical & social history questionnaire will need to be conducted as per Health Canada requirements, with the patient and/or most appropriate person(s).

6. In circumstances of donation after WLSM, the SOTD/CR will explain to the patient (if applicable), SDM, and/or family/substitute that donation will not proceed if DCC does not occur within the

period of time deemed acceptable for safe transplantation by the transplant team(s). In the event that donation is no longer possible, the continuation of end-of-life care will proceed as per the healthcare teams' normal palliative mechanisms.

If regionally appropriate, the SOTD/CR will explain that if lungs are accepted for transplant and DCC occurs within 3 to 24 hours, there may be potential to recover lungs through Non-Perfused Organ Donation (NPOD). Refer to CPI-9-226 *Non-Perfused Organ Donation Following DCD Attempt Process Instruction* for details.

7. To proceed with organ donation following DCC in circumstances of WLSM, the SOTD/CR informs the SDM and/or family/substitute that post-mortem donation requires pre-mortem testing for organ suitability (e.g., liver function tests, urinalysis, bronchoscopy, cardiac angiography, ABO, serology testing, and human leukocyte antigen). If applicable, the SOTD/CR will inform the SDM and/or family/substitute that a transfer to another healthcare facility may be indicated if certain organ suitability tests are unavailable on-site. In circumstances of MAID, see CPI-9-223 *Medical Assistance in Dying and Donation Process Instructions* for details.

8. The SOTDC/CR explains that pre-mortem interventions present minimal risk to the patient, and will not be used or continued if there is any indication that death will be accelerated as a result. If the patient, family/substitute(s), and/or SDM declines consent to pre-mortem interventions, the donation may still be facilitated, but the SOTD/CR explains that this will decrease the likelihood of successful graft function, and the SOTD/CR will request that the Clinical Services Coordinator (CSC) advise the transplant programs allocated organs in advance, to determine whether this affects their willingness to proceed with this provision.

9. The SOTD/CR informs the patient (if applicable), family/substitute, and/or SDM with the in-hospital location where WLSM or MAID provision is proposed, and the time and location where the family will be escorted from the area following the WLSM or MAID provision. If the patient (when applicable), family/substitute, and/or SDM objects to the proposed location, the donation may still be facilitated. However, the SOTD/CR explains that a delay related to transport to the OR might adversely impact the likelihood of successful graft function.

10. The SOTD/CR explains to the patient family/substitute, and/or SDM that if the transfer to the OR or the recovery surgery is delayed due to the family remaining with the deceased past the five-minute observation period to confirm DCC, donation may not proceed.

11. The SOTD/CR proceeds to obtain *Consent to Donate Organs and/or Tissues* (Exhibit 2) if the family/substitute, and/or SDM remains agreeable to donation following DCC after WLSM. See *Discussing Donation Opportunities and Documenting Consent Process Instruction, CPI-9-204*.

12. In circumstances of donation following DCC after a MAID Provision, the SOTD/CR proceeds to obtain *First-Person Consent to Donate Organs and/or Tissues* (Exhibit 3). See *Discussing Donation Opportunities and Documenting Consent Process Instruction, CPI-9-204*.

13. In addition to consenting to donate organs and/or tissues, the SOTD/CR proceeds to obtain consent from the patient, family/substitute, and/or SDM to allow the hospital and Ontario Health (TGLN) to use the donor's personal health information for the furthering of research into donation and transplantation after donation following DCC.

14. If the Coroner's consent is required, the SOTD/CR contacts the Coroner's office to obtain consent. See *Coroner's Case Process Instruction, CPI-9-203*.

15. The SOTD/CR will upload a copy of the following documents into the DMS (originals are left in the donor's chart):
    - For donation following DCC after WLSM:
        - *Consent to Interventions for the Purposes of Organ Donation after Death Determination by Circulatory Criteria; AND*
        - *Consent to Donate Organs and/or Tissues;* AND
        - Documentation of decision to WLSM; AND
        - (if applicable) *Permission for Donation in Death Investigation (Coroner/Forensic Pathologist Permission* form.
    - For donation following DCC after MAID provision:
        - See CPI-9-223 *Medical Assistance in Dying and Donation Process Instruction*

Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Consent to Interventions for the Purpose of Organ Donation after Death Determination by Circulatory Criteria	CSF-9-26	PRC	PRC	16 years
Donor Medical & Social History Questionnaire	CSF-9-14	PRC	PRC	16 years

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Consent Form to Donate: Organs and/or Tissues	CSF-9-11	PRC	PRC	16 years

References:

- *A brain-based definition of death and criteria for its determination after arrest of circulation or neurologic function in Canada: a 2023 clinical practice guideline*
- *Coroner's Case Process Instruction, CPI-9-203*
- *Discussing Donation Opportunities & Obtaining Consent Process Instruction, CPI-9-204*
- *DCD Consent Process Instruction, CPI-9-240*
- *Gift of Life Act*
- *Health Care Consent Act*
- *Medical Assistance in Dying and Donation Process Instruction, CPI-9-223*
- *Non-Perfused Organ Donation Following DCD Attempt Process Instruction, CPI-9-226*

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Exhibit 1: Consent to Interventions for the Purpose of Organ Donation after Death Determination by Circulatory Criteria
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CSF-9-26

Trillium Gift of Life Network

Consent to Interventions for the Purpose of Organ Donation after Death Determination by Circulatory Criteria

TGLN#_____ Page **1** of **3**

This form may be completed if the patient's death is imminent and in the opinion of a physician the patient is incapable of giving consent by reason of injury or disease. The patient's substitute decision-maker (SDM) according to the *Health Care Consent Act* must sign this form (Section A). If the patient's substitute under the *Gift of Life Act* differs from the SDM under the *Health Care Consent Act, the* patient's substitute under the *Gift of Life Act* must also sign this form (Section B).
See the *Guidelines Appendix* at the end of this document to determine the correct SDM under the *Health Care Consent Act* and the correct patient's substitute under the *Gift of Life Act*.

I consent to the following pre-mortem interventions to optimize the outcome of organs recovered for the purpose of organ donation after death determination by circulatory criteria. I understand that these interventions are not therapeutic for the patient. In the opinion of the physicians caring for the patient, these pre-mortem interventions present a minimal risk to the patient and will not be used or continued if there is any indication that death will be accelerated as a result. If death does not occur within an appropriate interval, I understand that organ recovery will not proceed, and that the patient will be transferred to an area for continuation of end of life care.

THE INTERVENTIONS REFERENCED ABOVE MAY INCLUDE:

- Tests and procedures including, but not limited to: ultrasound, bronchoscopy or cardiac angiogram required to determine the medical suitability, or to assist in matching of the organs and / or tissues for transplantation, including infectious disease blood testing to determine if there are any conditions that would prevent transplantation.
- A few minutes before or at the time of withdrawal of life sustaining measures, administration of medications to thin the blood, to prevent blood clots from forming within the organ(s).
- Insertion or maintenance of a gastric tube attached to suction to prevent food or liquids being breathed into the lungs or airways.

SPECIAL INSTRUCTIONS: _____

I also consent to the hospital and Ontario Health (Trillium Gift of Life Network [TGLN]) using the patient's personal information to further research into donation and transplantation after death determination by circulatory criteria. This research may include the collection of blood specimens. It may also include the following additional interventions.

DESCRIBE: _____

_____

483 Bay Street, South Tower, 4th Floor, Toronto ON, M5G 2C9
Provincial Resource Centre (24/7)
Tel: 416-363-4438 Toll Free 1-877-363-8456
Fax: 416-214-7797 Toll Free: 1-866-557-6100

September 27, 2023

Ontario Health
Trillium Gift of Life Network

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Exhibit 2: Consent to Donate Organs and/or Tissues
Page 1

CSF-9-11

Trillium Gift of Life Network

Consent to Donate Organs and/or Tissues

TGLN ID # _____ Page **1** of **3**

Select Applicable Consent Situation

☐ Patient's Substitute affirming/supporting the patient's documented consent to donate

☐ Patient's Substitute consenting on behalf of the patient because of belief that is what the patient would have wanted

☐ Documented patient's consent

A **TO BE COMPLETED BY THE PATIENT'S SUBSTITUTE**

I, _____ being the _____ of _____
NAME OF PATIENT'S SUBSTITUTE — CAPACITY OR RELATIONSHIP TO PATIENT — NAME OF PATIENT

Hereby consent to the removal of organs and/or tissues for the purpose of transplantation as indicated in the box below:

Donated Organ(s) and/or Tissue(s) – Please choose Option 1 or 2 by selecting the corresponding box below

☐ **Option 1** All organs and tissues listed below	☐ **Option 2** Only the organ(s) and/or tissue(s) selected (☑) below
☐ Heart ☐ Kidney ☐ Liver ☐ Vessels for future transplant ☐ Lung ☐ Pancreas ☐ Pancreas (for islets) ☐ Intestine	☐ Eyes ☐ Bone and Connective Tissue ☐ Heart for Valves; Pericardium; Aorta ☐ Skin

Additional donated organs or tissue for transplantation (please specify in writing if indicated)

☐ *Vascular Composite Allotransplantation (VCA) _____

*this type of transplantation has been explained to me

Initials: _____ _____ _____
INITIALS OF PATIENT'S SUBSTITUTE — DAY/MONTH/YEAR — TIME

☐ **Other _____

**this type of transplantation has been explained to me

Initials: _____ _____ _____
INITIALS OF PATIENT'S SUBSTITUTE — DAY/MONTH/YEAR — TIME

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Provincial Resource Centre (24/7)
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January 25, 2023

Ontario Health
Trillium Gift of Life Network

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Exhibit 3: First-Person Consent to Donate Organs and/or Tissues

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CSF-9-187

Trillium Gift of Life Network

First Person Consent to Donate Organs and/or Tissues

TGLN#_____ Page 1 of 4

A. **TO BE COMPLETED WITH PATIENT**

I, _____ , hereby consent to the removal of organs and/or tissues for the
NAME OF PATIENT (LEGAL FIRST AND LAST NAME)

purpose of transplantation as indicated in the box below:

Donated Organ(s) and/or Tissue(s) – Please choose Option 1 or 2 by selecting the corresponding box below

☐ **Option 1** All organs and tissues listed below	☐ **Option 2** Only the organ(s) and/or tissue(s) selected ((☑)) below
☐ Heart ☐ Kidney ☐ Liver ☐ Vessels for future transplant ☐ Lung ☐ Pancreas ☐ Pancreas (for islets) ☐ Intestine	☐ Eyes ☐ Bone and Connective Tissue ☐ Heart for Valves; Pericardium; Aorta ☐ Skin
Additional donated organs or tissue for transplantation (please specify in writing if indicated) ☐ **Other _____ **this type of transplantation has been explained to me Initials: _____ _____ INITIALS OF PATIENT DAY MONTH YEAR TIME	

My above gift(s) may also be used for the purpose(s) I have checked below:

☐ **None** ☐ **Medical Education** ☐ **Scientific Research**

I understand that donated organs/tissues/blood/fluids will be used only for Research Ethics Board-approved studies relate to donation and transplantation. Research may also include tissue connected to any of the organs or tissues identified above and also covers future research, which might include the possibility of stem cell or genetic research. I understand that Ontario Health (Trillium Gift of Life Network (TGLN)) will not be in a position to provide specific details on how the donated organs/tissues/blood/fluids may have been used.

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