

SECTION: Clinical ID NO.: CPI-9-204 PAGE: **1** of 16 ISSUE DATE: March 31, 2005 ISSUE.REVISION: 1.20 REVISION DATE: January 30, 2024 APPROVED BY: Hospital Program Authority

Clinical Process Instruction Manual

Discussing Donation Opportunities and Obtaining Consent Process Instruction

Policy:

Consent for post-mortem donation of organs or tissues may be given before or after death has been determined. A conscious patient prior to Medical Assistance in Dying (MAID), or in a Donation after Death Determination by Circulatory Criteria (DCC) scenario, may provide first person consent for post mortem donation. Where the patient cannot provide first person consent, or the patient's wishes for donation are not documented prior to death, the patient's substitute, hereafter referred to as "proxy", is supported in making a decision on behalf of the patient. The *Gift of Life Act* describes requirements for consent for organ and tissue donation in Ontario.

Identification of a patient's wish to donate as documented prior to death is encouraged before donation options are discussed with the patient or patient's family. The documented consent decision may be obtained from the Health Card Registered Persons Database (RPDB) administered by Service Ontario (SO), a signed donor card, another signed writing (e.g., will) or verbal communication by the patient as noted in writing by two witnesses. Donation consent decision registered *Donation Information - Ontario Organ and Tissue Donor Process Instruction, CPI-9-102.* The registered donation decision where available will be shared with the health care professional team for pre-approach planning and presented to the patient or donor family by the Trillium Gift of Life Network (TGLN) coordinator or designate when discussing the opportunity to donate. For the purposes of this Clinical Process Instruction (CPI), TGLN coordinator may refer to the Specialist - Organ and Tissue Donation (S-OTD), Clinical Responder (CR), Tissue Coordinator (TC), Referral Triage Coordinator (RTC), or Clinical Services Coordinator (CSC).

Where a patient is able to express consent to donation in the first person, this is the preferred method and a First Person Authorization (FPA) will be completed. Should the patient not be able to do so on their own behalf, a patient's consent to donate, documented in advance of death constitutes legal consent; however, in such situations it is accepted practice to consult with the patient or proxy in order to document affirmation of the patient's expressed consent to donate. Where the patient or available proxy does not affirm or support the patient's expressed consent to donate, TGLN will not proceed with the donation.

Where a proxy cannot be identified or located after reasonable efforts have been made to do so, TGLN may proceed with facilitating organ and/or tissue recovery for transplantation solely on the basis of the patient's expressed consent. Whenever TGLN proceeds with organ donation based on the patient's expressed consent, a copy of this documentation (e.g., a copy of the registered donation consent decision, donor card, FPA, etc.) is uploaded in the donor chart on iTransplant.



SECTION: Clinical ID NO.: CPI-9-204 PAGE: **2** of 16 ISSUE DATE: March 31, 2005 ISSUE.REVISION: 1.20 REVISION DATE: January 30, 2024 APPROVED BY: Hospital Program Authority

Clinical Process Instruction Manual

Discussing Donation Opportunities and Obtaining Consent Process Instruction

When the proxy is not present at the donor location but can be contacted, alternative means of communicating consent is possible. Consent for the use of donated organs and/or tissues in scientific research or education activities are secondary to consent for the purposes of transplantation. Where, prior to death, a patient has documented her/his consent to donate, such consent is to be interpreted as "for transplantation only" unless agreement to use donated organs and/or tissues for scientific research and/or education is expressly noted by the patient. If not expressly noted, the proxy may be asked to make a decision on behalf of the patient in this regard.

Consent for transfer of the potential donor to another site for surgical recovery or testing for the purposes of donation is required whenever such a transfer is necessary.

The completed *Consent Form to Donate: Organs and/or Tissues* authorizes TGLN and its partners in the donation process to access any of the patient's medical records, hospital or family physician and to conduct any testing necessary to determine the suitability of individual organs and tissues for transplantation.

Any combined organ-tissue or tissue exclusive multi-tissue donor consents conducted over the telephone shall be recorded or verified on a recorded line. This includes multi-tissue consents obtained over the telephone by the S-OTD, CR, TC or CSC in accordance with the telephone consent option in this CPI.

In non-designated hospitals, the TC obtains consent for tissue exclusive donors via telephone in accordance with the telephone consent option in this CPI.

Process:

- 1. The S-OTD, CR, RTC, CSC or TC establishes a pre-approach plan with the health care professional for inclusion of the opportunity to donate in end-of-life discussion with the patient and/or proxy. The pre-approach plan includes:
 - clarification of TGLN and hospital staff roles.
 - determine whether the patient's wishes for donation are known. If it is known that the
 patient has registered consent decision for organ and/or tissue donation, the S-OTD, CR
 or TC shares this information with the health care professional at this time. See Obtaining



SECTION: Clinical ID NO.: CPI-9-204 PAGE: **3** of 16 ISSUE DATE: March 31, 2005 ISSUE.REVISION: 1.20 REVISION DATE: January 30, 2024 APPROVED BY: Hospital Program Authority

Clinical Process Instruction Manual

Discussing Donation Opportunities and Obtaining Consent Process Instruction

Registered Donation Information – Ontario Organ and Tissue Donor Process Instruction, CPI-9-102.

- accurately identify the proxy if patient is not able to consent via FPA. Note: if the patient has documented consent, the same proxy is asked to affirm those wishes for donation.
- 2. The S-OTD, CR or TC ensures all appropriate persons are available to participate in the discussion. If the proxy is not known or cannot be located, the hospital is asked if any information about the following is available:
 - landlord
 - neighbours
 - financial/estate documents naming beneficiary,
 - previous medical records.

When someone dies in a hospital with no identified proxy, the hospital normally contacts the police to perform a search of the person's residence for information regarding next of kin or people of close relationship to the patient.

- 3. The RTC, CSC or TC obtains a hard copy of the patient's registered consent decision if available. For organ and/or tissue donors, the S-OTD or CR provides the CSC or RTC with a secure fax number for transmission of the registered donation consent, if required. The CSC or RTC ensures that the health card number is removed from the document prior to transmission.
- 4. For organ and/or tissue donors the S-OTD, CR, RTC, CSC or TC (and/or hospital staff) initiates the discussion with the patient and/or proxy in accordance with pre-approach plan established.
- 5. The S-OTD or CR will approach for organ and tissue donation at the same time. If the potential donor is ruled out for all organ donation, the S-OTD will obtain consent for tissue donation and, when appropriate, connect the proxy by telephone to a TC to complete the relevant *Donor Risk Assessment Interview(s)* (DRAI), as per *CPI-9-261 Medical* & *Social History Tissue Process Instruction*.
- 6. The S-OTD, CR or TC provides the patient or proxy with the information needed to make a decision about donation. Where the patient has died, the S-OTD, CR or TC provides the proxy with the information he/she needs to affirm the patient's wishes for donation, where patient's



SECTION: Clinical ID NO.: CPI-9-204 PAGE: **4** of 16 ISSUE DATE: March 31, 2005 ISSUE.REVISION: 1.20 REVISION DATE: January 30, 2024 APPROVED BY: Hospital Program Authority

Clinical Process Instruction Manual

Discussing Donation Opportunities and Obtaining Consent Process Instruction

consent decision was documented prior to death, or to make a decision about donation on behalf of the patient.

- 7. The following donation options are discussed with the patient or proxy, emphasizing that consent may be given for all organs and tissues listed on the TGLN consent form, or only for the organs and/or tissues specifically checked off on the form:
 - transplantation
 - research and education
 - research only
 - education only

Research may involve the recovery of tissues not listed on the TGLN consent form. In these circumstances, the TGLN coordinator obtaining consent will write the tissue on the consent form to indicate consent is provided for research. As part of the consent for research the coordinator reviews the details of consent for research including that:

- **donated organs/tissues/blood/fluids will be for research** related to donation and transplantation that has been approved by a Research Ethics Board.
- research also includes future research, which might include the possibility of stem cell or genetic research
- TGLN will not be in a position to provide specific details on how the donated organs/tissues/blood/fluids may have been used.

If recovered tissue cannot be used for any of the purposes specified in the consent, the tissue is to be processed as though no consent had been provided.

- 8. The TGLN coordinator selects the appropriate form for consent to donation.
 - 8.1. For obtaining consent via proxy, *Consent Form to Donate: Organs and/or Tissues* is used (see Exhibit 1 [English] and Exhibit 2 [French])
 - 8.2. For obtaining consent via FPA, *First-Person Consent to Donate Organs and/or Tissues* is used (see Exhibit 3 [English] and Exhibit 4 [French])
 - **Note:** References to *Consent Form to Donate: Organs and/or Tissues* in the remainder of this CPI refers to either consent form for proxy or FPA.



SECTION: Clinical ID NO.: CPI-9-204 PAGE: **5** of 16 ISSUE DATE: March 31, 2005 ISSUE.REVISION: 1.20 REVISION DATE: January 30, 2024 APPROVED BY: Hospital Program Authority

Clinical Process Instruction Manual

- 9. While completing the *Consent Form to Donate: Organs and/or Tissues*, the S-OTD, CR, RTC or TC confirms that the patient or proxy understands:
 - various options for donation for transplantation. Highlight only those relevant to the specific case.
 - option to donate for scientific research and/or education, in situations where organs and/or tissues are not suitable for transplantation.
 - option to donate organs and/or tissues not listed on the consent form specifically for scientific research and/or education. Note: highlight this only if there is an approved research or education project currently collecting tissue; see *Research and Education Activity Profiles* for more information. The S-OTD, CR or TC will fill in the organs/tissues if consent is obtained.
- 10. The S-OTD, CR or TC informs the patient or proxy that consent for donation includes authorization to access and review the patient's current and past medical records, and to do any tests or instructions needed to confirm the suitability of the organs and/or tissues for transplantation.
 - 10.1 Testing includes blood tests designed to detect the presence of infection that may be unsafe for the recipient(s), like human immunodeficiency virus (HIV), hepatitis B and C, and syphilis.
 - 10.2 If any of the donor screening tests are positive, the law requires TGLN to notify Public Health and provide the patient's name and the proxy's contact information for follow-up. If a positive test prevents transplantation from proceeding, TGLN will notify the proxy that the results of testing prevented transplantation, without providing a specific diagnosis.
 - 10.3 Donation involves surgical removal of the donated organs and/or tissues. Note: ensure the proxy has had all related questions answered to her/his satisfaction.
 - 10.4 The proxy may request that special considerations related to the donor or the donated organs and tissues be followed, such as accommodating a cultural or religious practice. Where transfer is required for surgical recovery, the patient's body will be released to the funeral home selected by the proxy, in the same manner as it would have been had transfer for surgical recovery not been necessary. There are no additional costs to the proxy as a result of the transfer.
 - 10.5 When consent for research is obtained, scientific research is approved by a Research Ethics Board and may include the possibility of stem cell research. The information on the research with donated tissue will not be available.



SECTION: Clinical ID NO.: CPI-9-204 PAGE: **6** of 16 ISSUE DATE: March 31, 2005 ISSUE.REVISION: 1.20 REVISION DATE: January 30, 2024 APPROVED BY: Hospital Program Authority

Clinical Process Instruction Manual

- 11. If the patient's wishes were known and documented before death, the S-OTD, CR or TC determines whether the proxy will affirm and support the patient's expressed wishes. The S-OTD, CR or TC provides the proxy with a copy or verbal confirmation if approach is done over the phone of the patient's preferences if available. Prior to providing a copy of the registered preferences, the S-OTD, CR or TC will ensure the health card number is not visible.
- 12. If the patient's wishes were not known before death, the S-OTD, CR or TC determines whether the proxy will give consent for donation on behalf of the patient.
- 13. If the option to donate is declined, the S-OTD, CR or TC explores and documents the reason in TGLN clinical notes, the database and the patient's hospital medical record if the S-OTD, CR or TC is on site (hospital permitting) given the proxy provides an explanation. If donation is declined, the S-OTD, CR or TC continues to provide support by ensuring the proxy is aware of the next steps in the hospital's process for end-of-life care and has access to information about making funeral arrangements and/or available bereavement support services.
- 14. If consent is obtained, the S-OTD, CR or TC or healthcare professional completes the *Consent Form to Donate: Organs and/or Tissues* with the patient/proxy, and witness the consent on the back of the form (*Part C and if applicable, Part D*).
- 15. If the proxy requests returning of organs to the body when not used for transplant, the S-OTD, CR documents this request on the *Consent Form to Donate: Organs and/or Tissues* in "Part B" of the form. The S-OTD or CR also documents this request in the donor chart under the tab "ORGAN PRE-OR", on the page "Donor Information", in the field titled "Planned Disposition of unused Organs or Tissues". The S-OTD or CR will advise the CSC whether there are any "return of organ(s) to the donor" restrictions before any offers are made to the transplant programs. The CSC will document "consent special instructions" on the shift report, when restrictions exist. If no request is made, check the "N/A" box for this field.
- 16. Where a proxy cannot be identified, but the patient's consent was documented in advance of death (e.g., donor card, health card, etc.), consent for donation is documented by the S -OTD, CR, RTC, CSC or TC or healthcare professional as follows:
 - Mark the appropriate box indicating the patient's documented consent.
 - *Part A:* complete "Donated Organ(s) and/or Tissue(s)" box based on the patient's documented wishes.



SECTION: Clinical ID NO.: CPI-9-204 PAGE: **7** of 16 ISSUE DATE: March 31, 2005 ISSUE.REVISION: 1.20 REVISION DATE: January 30, 2024 APPROVED BY: Hospital Program Authority

Clinical Process Instruction Manual

- indicate consent for use in scientific research and/or medical education only if such consent was specifically noted in the patient's documented consent.
- mark "N/A" in all remaining fields of Part A except the date field; note the date of the patient's death in the date field.
- *PartA*: Complete all fields except write "No proxy identified" on signature line for "appropriate legal authority".
- Part B, C: Complete in full.
- 17. Where the proxy is identified but will not be coming to the hospital, the S-OTD, CR, RTC, or TC may obtain consent via telephone by the proxy in the presence of at least two witnesses or on a recorded line.
- 18. All tissue exclusive consents obtained by the coordinators in the Provincial Resource Center (PRC) shall be done on recorded telephone lines.
- 19. All multi-tissue consents performed over the telephone by an S-OTD or CR outside of the PRC must be verified on a PRC recorded line prior to recovery.
- 20. The S-OTD or CR shall contact the PRC staff to notify that they are approaching a family for consent and that telephone verification would be required if multi-tissue is consented to. In situations where verification by PRC recorded line cannot be facilitated immediately, verification by a second witness may be completed without PRC recorded line to facilitate multi-tissue evaluation process. Verification with the SDM via PRC recorded line must be completed prior to recovery of multi-tissue. Verification over recorded line is not required if the consent is performed in person.
- 21. The first witness (the individual obtaining/affirming consent) will:
 - ask the proxy to identify her/himself and confirm their relationship to the donor
 - offer the proxy the option of having the consent form read to her/him in full
 - facilitate the conversation as outlined above
 - determine the donation decision as outlined above
 - document verbal consent for donation on the TGLN consent form as follows:
 - Part A: Complete all fields and select "Phone Consent" option.



SECTION: Clinical ID NO.: CPI-9-204 PAGE: **8** of 16 ISSUE DATE: March 31, 2005 ISSUE.REVISION: 1.20 REVISION DATE: January 30, 2024 APPROVED BY: Hospital Program Authority

Clinical Process Instruction Manual

Discussing Donation Opportunities and Obtaining Consent Process Instruction

Complete all fields for patient substitute name and address and select "Verbal/Phone Consent. Signature Not Applicable option.

- Part B: Complete in full as applicable.
- Part C: Complete in full and sign as the "individual obtaining/affirming consent"

22. After the first witness has documented consent, the second witness will:

- ask the proxy to identify her/himself and verify relationship to donor
- review the completed consent form with the proxy
- confirm the proxy's agreement with what is documented on the consent form, including what has been donated and any special considerations related to the donation
- sign the consent form as the "Second Witness affirming telephone consent" in Section D
- 23. The S-OTD, CR or call team member informs the family that a call centre representative will be contacting them to verify tissue consent over the phone, which is required for tissue recovery to proceed.
- 24. The S-OTD, CR asks the donor family if they require any additional support.
- 25. Where the S-OTD, CR or TC approaches over the phone, a 2nd person witnesses/confirms the consent. The S-OTD, CR or TC completes the *Consent Form to Donate: Organs and/or Tissues* and documents "telephone consent" on the form in lieu of the patients substitute signature.
- 26. Upon obtaining consent, the S-OTD, CR or TC reviews the completed consent form with the proxy and confirm her/his agreement with what is documented. For phone consents, the consent is read aloud concurrently with completion of consent form to confirm agreement with what the S-OTD, CR or TC is documenting.
- 27. For organ donors, the S-OTD or CR communicates with the CSC or RTC and conveys the outcome of the consent discussion with the CSC or RTC. When consent for multi-tissue is performed over the phone, the S-OTD, CR or call team member notifies the PRC to contact the family for telephone consent verification and provides the contact information. The S-OTD or CR proceeds to send a copy of the completed consent form to the PRC.



SECTION: Clinical ID NO.: CPI-9-204 PAGE: **9** of 16 ISSUE DATE: March 31, 2005 ISSUE.REVISION: 1.20 REVISION DATE: January 30, 2024 APPROVED BY: Hospital Program Authority

Clinical Process Instruction Manual

Discussing Donation Opportunities and Obtaining Consent Process Instruction

- In rare situations where consent was initially obtained without use of a recorded line, and family has requested no further contact by TGLN, the S-OTD will attempt additional interaction with family to review completed consent documentation over PRC recorded line or in person if possible.
- 28. TGLN is committed to ensuring that family decisions not to proceed further with the donation process, are clearly communicated internally and externally to:
 - Ensure the opportunity for tissue donation is not missed
 - Ensure that when family have stated they are not interested in any further communication, that they are not contacted again by TGLN.

TGLN is also committed to providing the family with appropriate communication from Family Services in "Consented Not Recovered and Declined Consent situations".

- Upon learning that the patient or family no longer desires to proceed with organ donation, an organ outcome of "consented not recovered" will be entered by the RTC/CSC.
- The S-OTD or CR in contact with the family or assigned to the case will document in the notes the reason the family rescinded consent for organ donation. Declined/rescinded consent decisions for organ donation can include, but are not limited to the following situations:
 - Family makes a request unsupported by policy to direct the donated organs and tissues (e.g., only would donate organs to a specific gender, race, creed, person not already on the waitlist, etc.)
 - Family makes a request that would unnecessarily delay recovery of organs (e.g., incur excessive warm ischemic time by delaying transport to an OR, delay skin cut, wants to spend more than 5 minutes after asystole, etc.)
- The S-OTD/CR/RTC/CSC receiving the information that the family has rescinded organ consent will immediately communicate to ALL organ team members and donor hospital staff to ensure the timely retraction of: transport, transplant team resources, hospital OR resources and TGLN resources, including couriers and provincial labs.
- The S-OTD or CR in contact with the family will affirm the Tissue Consent with the family to clearly understand the family's decision regarding tissue at patient asystole.



SECTION: Clinical ID NO.: CPI-9-204 PAGE: **10** of 16 ISSUE DATE: March 31, 2005 ISSUE.REVISION: 1.20 REVISION DATE: January 30, 2024 APPROVED BY: Hospital Program Authority

Clinical Process Instruction Manual

- The case status of tissue donation will be documented in iTransplant notes by the S-OTD or CR in contact with the family. The authorization page in iTransplant will be updated to "no".
- In addition to charting in iTransplant notes, a phone call or email will be sent to "TC" to communicate the same information.
- If the family agrees to proceed with tissue donation, the S-OTD/CR will phone the Tissue Team Lead (or delegate) to highlight the available suitability information in the patient's chart (physician assessment, med soc, timing of latest labs).
- The S-OTD/CR will communicate with the donor hospital staff, the need to call TGLN at time of death for Tissue Donation.
- If the family does not want to proceed with tissue donation the S-OTD/CR will phone the Tissue Team Lead (or delegate) to ensure that a call to the family <u>will not</u> be made at time of death for tissue consent.
- Family Services Follow up Directions In situations where Organ Outcome is consented not recovered and there has been no tissue approach due to nothing being suitable <u>OR</u> the tissue consent has also been rescinded no family follow up is warranted.
- NB: To notify family services that the family do <u>not</u> wish to be contacted, check the "Alert" box and enter details via the free text box. <u>DO NOT</u> check the "Do Not Contact" box.
- 29. The S-OTD/CR files the original, completed consent form in the patient's hospital medical record and attaches documentation of patient's wishes if available (e.g., copy of patient's registered preferences, donor card, etc.). For telephone consents where able to and as applicable, the TC sends the completed consent form to the hospital for filing in the patient chart.
- 30. The original consent form must accompany the potential donor to the referring hospital's OR, or if a transfer for surgical recovery is required to recovery hospital's OR. A copy of the completed consent form may be given to the proxy. A copy of the consent is uploaded in the TGLN donor chart on iTransplant.
- 31. For phone consents requiring call centre verification via a recorded line, the witness shall document in the clinical notes when verification is complete.
- 32. In situations where family has consented and the donor is a potential match for donation for composite tissue, once a potential match has been established, the S-OTD/CR will approach



SECTION: Clinical ID NO.: CPI-9-204 PAGE: **11** of 16 ISSUE DATE: March 31, 2005 ISSUE.REVISION: 1.20 REVISION DATE: January 30, 2024 APPROVED BY: Hospital Program Authority

Clinical Process Instruction Manual

Discussing Donation Opportunities and Obtaining Consent Process Instruction

families with the opportunity to donate specific composite tissue. The following information is reviewed with the family:

- what may be donated and who could be helped in general terms
- how matching is done (blood type, age, gender, size, skin tone and tissue matching)
- additional testing that may be required (including x-rays and assessment of circulation to the limb)
- any expected impact on timing of the organ donation process or funeral arrangements
- impact on funeral arrangement decisions, such as clothing, casket selection, or choice of viewing
- option of prosthesis post recovery
- confidentiality and potential for media attention with recipient images
- 33. Any amendments to a signed consent form must be dated and initialed by the patient substitute. When an amendment to a consent form is completed by telephone, a second witness must sign on the back of the form in *Part D*. In situations where the original consent was completed by telephone, and amendments to the consent are made, it is recommended to fully complete a new consent form to replace the original consent.
- 34. In the case of "composite tissue" or "other" donation, the specific composite tissue, for example, "right hand and arm" must be written in the space provided.

| Records | | | | |
|--|-----------------------------|---------------|--------------------|--|
| Record Name | Form No. (if applicable) | Record Holder | Record Location | Record Retention Time (as a minimum) |
| Consent Form to Donate: Organs and/or Tissues (English) | CSF-9-11 | PRC | PRC | 16 years |



SECTION: Clinical ID NO.: CPI-9-204 PAGE: **12** of 16 ISSUE DATE: March 31, 2005 ISSUE.REVISION: 1.20 REVISION DATE: January 30, 2024 APPROVED BY: Hospital Program Authority

Clinical Process Instruction Manual

| Record Name | Form No. (if applicable) | Record Holder | Record Location | Record Retention Time (as a minimum) |
|---|-----------------------------|---------------|--------------------|--|
| Consent Form to Donate: Organs and/or Tissues (French) | CSF-9-12 | PRC | PRC | 16 years |
| First Person Consent to Donate Organs and or Tissues (English) | CSF-9-187 | PRC | PRC | 16 years |
| First Person Consent to Donate Organs and or Tissues (French) | CSF-9-193 | PRC | PRC | 16 years |
| Eye-Only Donor Risk Assessment Interview (Donor > 10 years old) | CSF-9-214 | PRC | PRC | 16 years |
| Eye-Only Donor Risk Assessment Interview (Child Donor ≤ 10 years old) | CSF-9-215 | PRC | PRC | 16 years |
| Eye-Only Donor Risk Assessment Interview Birth Mother | CSF-9-216 | PRC | PRC | 16 years |
| Donor Risk Assessment Interview (Donor > 10 years old) | CSF-9-261 | PRC | PRC | 16 years |



SECTION: Clinical ID NO.: CPI-9-204 PAGE: **13** of 16 ISSUE DATE: March 31, 2005 ISSUE.REVISION: 1.20 REVISION DATE: January 30, 2024 APPROVED BY: Hospital Program Authority

Clinical Process Instruction Manual

Discussing Donation Opportunities and Obtaining Consent Process Instruction

| Record Name | Form No. (if applicable) | Record Holder | Record Location | Record Retention Time (as a minimum) |
|--|-----------------------------|---------------|--------------------|--|
| Donor Risk Assessment Interview (Child Donor ≤ 10 years old) | CSF-9-262 | PRC | PRC | 16 years |
| Donor Risk Assessment Interview Birth Mother | CSF-9-263 | PRC | PRC | 16 years |

References:

- Obtaining Registered Donation Information Ontario Organ and Tissue Donor Process Instruction, CPI-9-102
- Infectious Disease Testing STAT Process Instruction, CPI-9-211
- Medical & Social History Tissue, CPI-9-261
- Gift of Life Act, R.S.O. 1990, Chapter H.20, Part II.1
- Health Canada. Canada Gazette, Part 2. Safety of Human Cells, Tissues, and Organs for Transplantation Regulations. Wed Jun 27, 2007
- Franz HG, DeJong W, Wolfe SM, Nathan H, Payne D, Reltsma W, Beasley C. Explaining brain death: a critical feature of the donation process. Journal of Transplant Coordination 1997; Vol 7, No.1 14-21
- Siminoff L.A, Lawrence, RH, Zhang A. Decoupling: What is it and does it really help increase consent to organ donation? Transplantation March 2002; Vol 12, No.1
- Verble M, Worth J. Adequate consent: its content in the donation discussion. Journal of Transplant Coordination 1998; Vol 8 99-104
- Online Resource Centre



SECTION: Clinical ID NO.: CPI-9-204 PAGE: **14** of 16 ISSUE DATE: March 31, 2005 ISSUE.REVISION: 1.20 REVISION DATE: January 30, 2024 APPROVED BY: Hospital Program Authority

Clinical Process Instruction Manual

Discussing Donation Opportunities and Obtaining Consent Process Instruction

• Standards for Tissue Banking, American Association of Tissue Banks, United States, 14th edition, 2017. D2.000



SECTION: Clinical ID NO.: CPI-9-204 PAGE: **15** of 16 ISSUE DATE: March 31, 2005 ISSUE.REVISION: 1.20 REVISION DATE: January 30, 2024 APPROVED BY: Hospital Program Authority

Clinical Process Instruction Manual

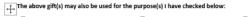
Discussing Donation Opportunities and Obtaining Consent Process Instruction

Exhibit 1: Consent Form to Donate: Organs and/or Tissues (English)

Page

1

| | | | | | CSF-9-11 |
|--|--|---|--|---|--|
| Trillium Gift of Life Network | | | | | |
| Consent to | o Donate Or | gans and | l/or Tissue | s | |
| IGLN ID # | | | | | Page 1 of 3 |
| elect Applicable Consent Situation | | | | | |
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| A | ing the | CODE ARCASLE YO R | of | | New Los NATINA |
| NAME OF PATENT'S SAMPTUTE | | | | | |
| ereby consent to the removal of organs and/o onated Organ(s) and/or Tissue(s) – Please che Option 1 | oose Option 1 or 2 | by selecting t | he corresponding | box bel Option | ow n 2 |
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| Abuse D Partor Lammar tereby consent to the removal of organs and/o bonated Organ(s) and/or Tissue(s) – Please ch option 1 All organs and tissues listed bel Heart Kidney Liver Vessels for future transplant Lung Pancreas Pancreas (or islets) | ansplantation (VCA) | by selecting t | e orresponding e organ(s) and/or Eyes Bone and Conn Heart for Valve Skin | box belo Option tissue(s) ective 1 s; Peric | ow n 2 j selected (⊠) below |
| ABAGE & PARTON SAMPTON Interesting and Antiperson antiperson antiperson antiperson antiperson antiperson antiperson | ansplantation (ple ntation (VCA) n explained to me | by selecting the | e orresponding e organ(s) and/or Eyes Bone and Conn Heart for Valve Skin | box belo Option tissue(s) ective 1 s; Peric | ow n 2 j selected (⊠) below |
| hade or benefits and/or spans and/or spans and/or spans and or spans and/or spans and/or organs, and/or Tissue(s) - Please characteristic of the spans and tissues listed below the spans and tissues listed below the spans and tissues and the spans and tissues (or listers) and the spans or tissue for transplant and the spans of tissues for the spans and tissues are spans and the spans are spans and the spans are spans or tissue for transplant and the spans of the s | ansplantation (pi4 ntation (vCA) n explained to me | by selecting to Only th Control to Control t | e orresponding e organ(s) and/or Eyes Bone and Conn Heart for Valve Skin n writing if indica | box belo Option tissue(s) ective 1 s; Peric | ow n Z selected (⊠} below Tissue ardium; Aorta |







SECTION: Clinical ID NO.: CPI-9-204 PAGE: **16** of 16 ISSUE DATE: March 31, 2005 ISSUE.REVISION: 1.20 REVISION DATE: January 30, 2024 APPROVED BY: Hospital Program Authority

Clinical Process Instruction Manual

Discussing Donation Opportunities and Obtaining Consent Process Instruction

Exhibit 2: Consent Form to Donate: Organs and/or Tissues (French)

Page 1

| | CSF-9-12 |
|---|--|
| Réseau | |
| Trillium pour | |
| | |
| le don de vie | |
| Concontoment | au don d'organes et / ou de tissus |
| N ⁰ Identification attribué par le RTDV | |
| | Page 1/ |
| sélectionner le consentement pertinent | |
| confirme/appuie le consentement au don documenté du patient. | Le décideur substitut du patient consent au don au nom du patient parce qu'il parse que c'est ce que le patient aurait voulu. |
| À FAIRE REMPLIR PAR LE DÉCIDEUR SUBSTITUT DU F | PATIENT |
| En vertu de la présente, je, soussigné(e), | Νακου Ολατική Sustain |
| à titre de | Now au Deaneur Sueamur |
| Litin Avec Le | Now Du Partour |
| Consens au prélèvement des organes et / ou tissus o | |
| | on – Veuillez choisir l'option 1 ou 2 en cochant la case correspondante |
| Option 1 Tous les organes et tissus désignés | □ Option 2 Organe(s) et/ou tissu(s) cochés (☑) seulement |
| Cœur | Yeux |
| Coeur Rein | _ |
| Kein Foie | Os et tissus conjonctifs Cœur pour valvules, péricarde, aorte |
| Vaisseaux pour transplantations future | |
| Vaisseaux pour transplantations tuture Poumon | is 🗆 Feau |
| Pancréas | |
| Pancréas (pour îlots) | |
| Intestin | |
| | ansplantation (veuillez préciser par écrit, le cas échéant) |
| Allogreffe de tissus composites vasce | |
| *ce type de transplantation m'a été expliqué | |
| Initiales: | |
| INITIALES DU DÉCIDEUR SUBSTITUT DU PATIENT | JOUR MOIS ANNÉE HEURE |
| **Autre | |
| *ce type de transplantation m'a été expliqué | |
| Initiales: | |
| INITIALES DU DÉCIDEUR SUBSTITUT DU PATIENT | JOUR MOIS ANNÉE HEURE |
| | |
| 483 rue Bay, tour Sud, 4e étage, Toronto ON, M5G 2C9 | |
| Tél : 416-363-4438 Numéro sans frais : 1-877-363-8456 | Santé Ontario |
| Télée: 416-214-7797 Numéro sans frais : 1-866-557-6100 | Réseau Trillium pour le don de |
| January 25, 2023 | Nesedu minum pour le doir de |



SECTION: Clinical ID NO.: CPI-9-204 PAGE: **17** of 16 ISSUE DATE: March 31, 2005 ISSUE.REVISION: 1.20 REVISION DATE: January 30, 2024 APPROVED BY: Hospital Program Authority

Clinical Process Instruction Manual

Page 1

Discussing Donation Opportunities and Obtaining Consent Process Instruction

Exhibit 3: First Person Consent Form to Donate: Organs and/or Tissues (English)

| TGLN# | d in the box below: lease choose Option 1 or 2 | he removal of organs and 2 by selecting the corresp Only the organ(s) a Eyes | Page 1 of 4 d/or tissues for the ponding box below c option 2 | | | | |
|--|---|---|--|--|--|--|--|
| Ketwork First Pers TGLN# To as commercial with extense ' To as commercial with extense ' more chemory plane to an out carrent) purpose of transplantation as indicated Donated Organ(s) and/or Tissue(s) - P | , hereby consent to th i in the box below: lease choose Option 1 or 2 | he removal of organs and 2 by selecting the corresp Only the organ(s) a Eyes | Page 1 of 4 d/or tissues for the ponding box below c option 2 | | | | |
| First Pers TGLN# To be completed with PATIENT I, | , hereby consent to th i in the box below: lease choose Option 1 or 2 | he removal of organs and 2 by selecting the corresp Only the organ(s) a Eyes | Page 1 of 4 d/or tissues for the ponding box below c option 2 | | | | |
| TGLN# To ac compute D with PATIENT | , hereby consent to th i in the box below: lease choose Option 1 or 2 | he removal of organs and 2 by selecting the corresp Only the organ(s) a Eyes | Page 1 of 4 d/or tissues for the ponding box below c option 2 | | | | |
| TGLN# To ac compute D with PATIENT | , hereby consent to th i in the box below: lease choose Option 1 or 2 | he removal of organs and 2 by selecting the corresp Only the organ(s) a Eyes | Page 1 of 4 d/or tissues for the ponding box below c option 2 | | | | |
| To BE COMPLETED WITH PATIENT I, | d in the box below: lease choose Option 1 or 2 | 2 by selecting the corres Only the organ(s) a Univ the organ(s) a | d/or tissues for the ponding box below Option 2 | | | | |
| Image Answer Base, here set Largest purpose of transplantation as indicated Donated Organ(s) and/or Tissue(s) – P Image Option 1 All organs and tissues life Heart Kidney Liver Vessels for future transplantation Pancreas Pancreas Pancreas Intestine Additional donated organs or tissue **this type of transplantation Initials: Dartest future transplantation. Initials: Dartest future transplantation. Initials: Additional donated organs or tissue Covers future research, which might incl Indexton d that donated organs/tissue Initials: Dartest future research, which might incl (Trillium Gift of Life Network (TGLN)) | d in the box below: lease choose Option 1 or 2 | 2 by selecting the corres Only the organ(s) a Univ the organ(s) a | ponding box below | | | | |
| Donated Organ(s) and/or Tissue(s) - P Option 1 All organs and tissues li Heart Kidney Uver Vessels for future trans Lung Pancreas Pancreas (for islets) Intestine Additional donated organs or tissue +* this type of transplantation Initials: TRADUSCOF ALLEM My above gift(s) may also be used fo None I understand that donated organs/tissue donation and transplantation. Research covers future research, which might incl (Trillium Git of Life Network (TGLN)) | d in the box below: lease choose Option 1 or 2 | 2 by selecting the corres Only the organ(s) a Univ the organ(s) a | ponding box below | | | | |
| Donated Organ(s) and/or Tissue(s) P | lease choose Option 1 or 2 | Only the organ(s) a | Option 2 | | | | |
| All organs and tissues li Kidney Liver Vessels for future trans Lung Pancreas Pancreas (for islets) Intestine Additional donated organs or tissue **Other **Other **This type of transplantation Initials: TREPULS OF PATTERT My above gift(s) may also be used fo None I understand that donated organs/tissue donation and transplantation. Research covers future research, which might incl (Trillium Gift of Life Network (TGLN)) | | Only the organ(s) a | Option 2 | | | | |
| All organs and tissues li Ald tiver Curver Curver Curver Content Curver Content Curver Curve | | Eyes | | | | | |
| Kidney Liver Vessels for future trans Lung Pancreas Pancreas Pancreas Pancreas (for islets) Intestine Additional donated organs or tissue "**Other **Other **Other **Other works of transplantation Initials: Tartust of PARIENT My above gift(s) may also be used for None I understand that donated organs/tissue donation and transplantation. Research which might ind (rillium dif to Life Network (TGLN)) will | | , | and/or tissue(s) selected ((덴)) belo | | | | |
| Liver Liver Vessels for future trans Lung Pancreas Pancreas (for islets) Intestine Additional donated organs or tissue **this type of transplantation Initials: TREFMLS OF PARENT My above gift(s) may also be used fo None I understand that donated organs/tissue donation and transplantation. Research covers future research, which might incl (Trillium Git of Life Network (TGLN)) | | | | | | | |
| Vessels for future trans Lung Pancreas Pancreas (for islets) Intestine Additional donated organs or tissue **Other **This type of transplantation Initials: TeamALS OF PARTIENT My above gift(s) may also be used fo None I understand that donated organs/tissue donation and transplantation. Research covers future research, which might incl (Trillium Gift of Life Network (TGLN)) | | | nd Connective Tissue | | | | |
| Lung Pancreas Pancreas Pancreas Intestine Additional donated organs or tissue **Other **Other **This type of transplantation Initials: TatUAGOF FATERIT My above gift(s) may also be used fo None I understand that donated organs/tissue donation and transplantation. Research covers future research, which might incl (Trillium Git of Life Network (TGLN)) will | | | or Valves; Pericardium; Aorta | | | | |
| Pancreas Pancreas (for islets) Intestine Additional donated organs or tissue **this type of transplantation Initials: ##TURSCOFENTERM My above gift(s) may also be used for None I understand that donated organs/tissue donation and transplantation. Research which might incl (rillium cift of Life Network (TGLN)) will | plant | 🗌 Skin | | | | | |
| Pancreas (for islets) Intestine Additional donated organs or tissue ··Other | | | | | | | |
| Intestine Intestine Additional donated organs or tissue Intials: | | | | | | | |
| Additional donated organs or tissue | | | | | | | |
| **this type of transplantation Initials: BRITWLS OF PAYBRIT My above gift(s) may also be used for None I understand that donated organs/tissue donation and transplantation. Research covers future research, which might incl (Trillium Gift of Life Network (TGLN)) will | Intestine Additional donated organs or tissue for transplantation (please specify in writing if indicated) | | | | | | |
| **this type of transplantation Initials: My above gift(s) may also be used fo None I understand that donated organs/tissue donation and transplantation. Research covers future research, which might incl (Trillium Git of Life Network (TGLN)) will | | | | | | | |
| HITWASCHFATEHT My above gift(s) may also be used fo None Understand that donated organs/tissue donation and transplantation. Research covers future research, which might ind (Trillium Gift of Life Network (TGLN)) will | has been explained to me | | | | | | |
| My above gift(s) may also be used for None I understand that donated organs/tissue donation and transplantation. Research covers future research, which might incl (Trillium Git of Life Network (TGLN)) will | | | | | | | |
| None I understand that donated organs/tissue donation and transplantation. Research covers future research, which might ind (Trillium Gitt of Life Network (TGLN)) will | | | | | | | |
| I understand that donated organs/tissue donation and transplantation. Research covers future research, which might incl (Trillium Gift of Life Network (TGLN)) wil | or the purpose(s) I have | | | | | | |
| donation and transplantation. Research covers future research, which might incl (Trillium Gift of Life Network (TGLN)) wil | Medical Education | on 🗆 Scie | entific Research | | | | |
| covers future research, which might incl (Trillium Gift of Life Network (TGLN)) wil | 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 a | | | | | | |
| (Trillium Gift of Life Network (TGLN)) wil | | | | | | | |
| organs/tissues/blood/fluids may have b | 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 | | | | | | |
| | en used. | | | | | | |
| | | | | | | | |
| 483 Bay Street, South Tower, 4th Floor, Toronto D | | | | | | | |
| Provincial Resource Centre (24/7) Tel: 416-363-4438 Toll Free 1-877-363-8456 | N, M5G 2C9 | \$2 | Ontario Healt | | | | |
| Fax: 416-214-7797 Toll Free: 1-866-557-6100 | N, M5G 2C9 | | Trillium Gift of Life N | | | | |
| January 25, 2023 | N, M5G 2C9 | | | | | | |



SECTION: Clinical ID NO.: CPI-9-204 PAGE: **18** of 16 ISSUE DATE: March 31, 2005 ISSUE.REVISION: 1.20 REVISION DATE: January 30, 2024 APPROVED BY: Hospital Program Authority

Clinical Process Instruction Manual

Discussing Donation Opportunities and Obtaining Consent Process Instruction

Exhibit 4: First Person Consent Form to Donate: Organs and/or Tissues (French)

Page 1

| | Réseau Trillium po le don de v | ur ie | | | | CSF-9-193 |
|--|--|--|--|----------------------------|---|--|
| | Co | nsentement de | la première | pe | rsonne au do | on |
| | | | es et / ou d | | | |
| Nº ID DU RTI | DV : | _ | | | | Page 1/4 |
| A COMPLETE | R AVEC LE PATIEN | r | | | | |
| Je, | | | consens par les | prése | entes au prélèvemen | t d'organes et/ou de tissus |
| - | | OM ET NOM DE FAMILE) | | | | - |
| aux fins de t | transplantation con | nme indiqué dans la case | ci-dessous. | | | |
| On | zane(s) et / ou tissu | (s) faisant l'objet de don - | Veuillez choisir l'o | otion | 1 ou 2 en cochant la | case correspondante |
| | | Option 1 | | | | ption 2 |
| | | s et tissus désignés | | Orga | | cochés (🗹) seulement |
| | Cœur | _ | | П | Yeux | |
| | Rein | | | _ | Os et tissus conjo | octife |
| | Foie | | | _ | | es, péricarde, aorte |
| | | | | _ | Peau Peau | es, pericarde, aorte |
| | Poumon | ns de transplantation f | Jture | | Peau | |
| | Poumon Pancréas | | | | | |
| I = | | | | | | |
| | Pancréas (pour i | iots) | | | | |
| | Intestin | nnés aux fins de transpl | | , | | (|
| | tiales : | lantation m'a été explic | jué | R | Mos Anne | Haun |
| Mes dons p | récités peuvent a | ussi être utilisés aux fi | ns que i'ai coché | es ci- | dessous : | |
| | - | _ | | | _ | |
| Aucune | • | Enseign | ement de la méde | cine | Recherche s | cientifique |
| d'éthique de des organes d'une étude | la recherche porta ou tissus identifiés sur les cellules soud | nt sur le don et la transpla ci-dessus et s'étend égale | ntation. La recher ment aux travaux o mprends que Sant | che pe de rec :é Ont | eut également inclur herche futurs, qui po tario, Réseau Trillium | es approuvées par le Comité e des tissus connectés à l'un ourraient inclure la possibilité I pour le don de vie (RTDV), ne onnés peuvent avoir été |
| Tél : 416-363-44 Téléc: 416-214-3 | r Sud, 4e étage, Toronti 38 Numéro sans frais : 1 1797 Numéro sans frais | -877-363-8456 | | Ŷ | Santé O Réseau Trilliu | Intario um pour le don de vie |
| January 25, 202 | 8 | | | | | |
| | | | | | | |