Clinical Process Instruction Manual

Donor Assessment – Combined Organ and Tissue Process Instruction

Policy:

The accurate and appropriate assessment of a potential organ and tissue donor is an essential step in the donation process to help minimize risk of disease transmission and other adverse outcomes associated with transplantation. This process is a combined effort of health care professionals, and Trillium Gift of Life Network's (TGLN) Referral Triage Coordinators (RTC), Clinical Services Coordinators (CSC), Tissue Coordinators (TC), Clinical Responders (CR) and/or Specialist - Organ and Tissue Donation (S-OTD) in consultation with TGLN's Chief Medical Officer (CMO) or on-call designate, transplant physicians and/or tissue banks.

For the purposes of this document, TGLN coordinator refers to the S-OTD or TC, but in some instances the CSC, CR or Clinical Specialist (CS) may fill this role.

A combination of a thorough review of the potential donor's medical record and a completed donor Medical and Social History Questionnaire (MSHx) is essential in gathering past medical history and clinical data related to critical illness/trauma (see *Donor Medical and Social History – Organ or Combined Organ & Tissue Process Instruction, CPI-9-207*). This information is collected, stored and made available to transplant programs and tissue banks as appropriate. iTransplant as well as the *Assessment Form: Organ/Combined Organ & Tissue Donor or Assessment Form: Tissue Donor* (see Exhibits 1 and 2) may be used to collect and store relevant data.

Screening and testing is to be facilitated as quickly and efficiently as possible. However, specimen collection and specialized testing to evaluate organ and/or tissue suitability are not performed until consent for donation is documented. The exception to this is that testing may proceed for organ donors if next-of-kin (NOK) give approval to do so in advance of documented consent.

Most 'contraindications' to organ donation are not absolute. In these situations, exceptional distribution (EXD) provisions may apply. See *Exceptional Distribution Process Instruction, CPI-9-217* for a complete list of these conditions. If it is not predetermined, as above, TGLN's CMO or on-call designate will determine whether an offer for an organ falls under EXD circumstances. Organs that are safe for transplantation, are offered by the CSC on behalf of CMO-Transplant. The organs are considered safe for transplantation when they are processed in accordance with Health Canada regulations. Organs that are not considered safe for transplant by Health Canada's Cells, Tissues and Organs (CTO) regulations can be exceptionally distributed if they have exclusionary criteria. A preliminary discussion with relevant transplant programs in order to assess interest in potential organs for transplantation may be necessary.

Tissue donation may also be possible despite the presence of 'adverse conditions'. However, TGLN will not proceed with donation of tissues for transplantation if absolute contraindications are present (see *General Tissue Donation Criteria and Contraindications, CPI-9-262*) or if tissue bank specific criteria are not met.

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The decision to accept organs and/or tissues following an offer from TGLN rests with the transplant programs and/or tissue banks receiving the offer. Some Tissue Banks have designated the authority to accept tissue on their behalf to TGLN.

Process:

When a potential donor has been identified and referred, preliminary medical suitability determination begins. Once preliminary medical suitability for absolute exclusions is confirmed, a more comprehensive donor assessment process is undertaken by a TGLN coordinator. The following procedure is divided into three parts – Part A: Determining Preliminary Medical Suitability, Part B: Organ or Combined Organ and Tissue Donation, and Part C: Tissue-Only Donation.

PART A: Determining Preliminary Medical Suitability

1. On receiving a referral of a potential organ donor, the RTC or designate will enter relevant preliminary data into iTransplant and/or complete the *Triage Form.*

2. At time of referral, the RTC or CSC will obtain the following information and enter it into iTransplant. If the referral is from an S-OTD hospital or if an S-OTD or CR is on site, the S-OTD or CR may be assigned to obtain this information. Any available updates to this information will be entered into iTransplant each time the S-OTD or RTC follows up on an open referral.
   2.1. Admission history including history of cardiac arrest and downtime
   2.2. Medical history including cancer history if applicable
   2.3. Brainstem reflexes
   2.4. Chemistry
   2.5. CBC
   2.6. ABGs and CXR results
   2.7. Vital signs including ventilator settings
   2.8. The RTC or S-OTD will make a clinical note documenting the patient's neurological status, plan of care, any relevant family dynamics and any changes since the last follow up.

3. The RTC and/or S-OTD determine preliminary medical suitability for donation prior to the donation discussion with the NOK for absolute exclusions only. When death has been determined by neurologic criteria and consent obtained or a pre-mortem consent for the purposes of donation after death determination by circulatory criteria (DCC) is obtained, the donation process begins, and medical suitability of the potential donor is further evaluated.

4. The S-OTD or designate will complete the assessment of the donor using the following:
   - chart review with patient identification verification (first and last name, date-of-birth (DOB) and medical record number (MRN));

- *If evidence of cancer is noted, obtain the following reports (if available): operative notes, pathology reports, cancer care treatment protocols, follow-up care, follow-up imaging reports*
- *Review case with TSP to discuss any additional testing/imaging and/or interest calls as needed*

- donor medical and social history questionnaire*;*
- physical examination for trauma and evidence of high-risk behavior, signs of malignancy, infection and/or trauma to the retrieval site.

5. If proceeding with donation would contravene relevant standards, the TGLN coordinator will consult *Exceptional Distribution Process Instruction, CPI-9-217* and/or TGLN's CMO or on-call designate to determine whether or not an EXD circumstance is present prior to offering organs. The coordinator will advise the CMO or on-call designate regarding any extenuating circumstances such as high status or seropositive potential organ recipients, as applicable.

6. If the coordinator or CMO or on-call designate determines that organs should be offered with respect to EXD provisions, the coordinator will contact the relevant transplant programs to determine if they will accept such offers, documenting as appropriate in accordance with the *Exceptional Distribution Process Instruction, CPI-9-217.*

7. In some cases, it may be necessary for the coordinator to conduct a preliminary conversation with transplant programs for interest in organ(s) for transplantation. For instance, to address resource issues such as donor work-up and/or recovery, requests for delay or acceleration of process, discussion and verification of medical status, etc. The coordinator will advise the transplant program that the call is intended to assess preliminary interest in organ(s) for transplantation, and is not to be construed as an organ offer or allocation.

7.1. In addition to the information collected at time of referral and on daily updates (see 2.1 through 2.8), the following information will be required for an interest call:
- Height
- Weight
- ABO (if available)
- Abdominal imaging (if available)
- CXR image
- Positive cultures and treatment if applicable
- Medications

7.2. For patients with a history of cancer a, TSP call should only be completed after completing a review of hospital and family doctor records for the following details:
7.2.1. Cancer diagnosis and date

7.2.2. Treatment details and dates
7.2.3. Follow-up details
7.2.4. Surgical and pathology notes if applicable
7.2.5. Any other available info about the cancer history

Contraindications to donation are outlined in *Exceptional Distribution Process Instruction, CPI-9-217.*

All organs, that are safe for transplantation, are offered by the CSC on behalf of CMO-Transplant. The organs are considered safe for transplantation when they are processed in accordance with Health Canada regulations. Organs not deemed suitable for transplant can be EXD if they have exclusionary criteria.

8. After interest has been confirmed for composite tissue with the transplant program, the coordinator will approach family for consent for composite tissue if the discussion did not occur during the primary donation discussion.

9. For contraindications specific to particular tissue banks, see *Tissue Bank Profiles* on the Online Resource Centre (ORC).

PART B: Organ or Combined Organ and Tissue Donation

The TGLN coordinator will gather all relevant donor information including the following:

Note: Where a coordinator is present on-site, information shall be communicated to the Provincial Resource Centre (PRC) coordinator in a timely manner.

10. Referral:
The coordinator will record the name and contact number for the referring individual.

11. Non-Ontario Offer:
Preliminary information pertaining to organ offers from other programs, and information related to any primary/backup offers, i.e.: Operating Room (OR) time, organs being recovered, whether there is an EXD, and the reason why is also recorded. See *Non-Ontario Organ Donation, CPI-9-101*.

12. Donor Information:
The coordinator will validate the donor's identification and verify it with the assigned TGLN donor number. See *Donation Support Process Instruction, CPI-9-103*. Donor information collected and documented includes:

- First and last name

- DOB
- MRN
- the cause-of-death or diagnosis (as applicable),
- admission height,
- admission weight,
- age,
- ABO type and subtype if donor is A or AB (if subtyping is available),
- total lung capacity (TLC),
- date and time of death,
- coroner's case and if so, was the coroner's permission obtained

If an autopsy is planned, the location of the planned autopsy and the planned disposition of any unused organs or tissues are also documented. Refer to *Coroner's Case Process Instruction, CPI-9-203* to determine how results are obtained and reported.

13. Admission History*:*
The coordinator will obtain required information from the potential donor's hospital medical record including Emergency Medical Service (EMS) forms, physician's notes, and Emergency Department (ED) and Intensive Care Unit (ICU) flow sheets. Include admission details, intubation date and time, whether the intubation was traumatic, any arrests and/or cardiopulmonary resuscitation (CPR)/defibrillation, resuscitation drugs, duration of the arrest, trauma and/or surgery during this admission.

14. Drug Screen:
Unless the possibility of an overdose is ruled out by the physician, drug screening (blood and urine) should be considered for potential donors hospitalized less than 48 hours, and those with questionable medical/social histories or unknown cause-of-death. The S-OTD and/or CSC notes any sedatives/medications previously administered which may test positive in any drug screen. If the donor hospital cannot perform an adequate drug screen, Hospital for Sick Children (HSC) toxicology department may be utilized. See Exhibit 3 for the *HSC Toxicology Form.*

Note: If the donor is being transferred to another hospital for recovery, the S-OTD, in collaboration with the CSC, will consider the receiving hospital's protocols regarding drug screening prior to death determination by neurologic criteria (DNC).

15. Previous Positive Cultures:

Any positive cultures obtained during this admission and prior to consent should be documented, including the source (blood, urine, sputum, etc.), the results, and any treatment provided.

16. Medications:
    The S-OTD or designate documents medications administered from the time of consent to organ recovery.(The medications administered prior to hospitalization (home meds including supplements will be captured in the donor's medical social history questionnaire or the patient's medical record).

    Medications administered in the hospital to be documented include the following:
    - Hemodynamic agents (i.e. vasopressors, inotropes)/Cardiovascular agents (i.e. antihypertensives)
    - Antibiotics, Antifungals and Antivirals
    - Immune Modulating Agents (i.e. immunosuppressants and steroids)
    - Blood glucose regulators
    - Anticoagulants
    - Hormonal agents (i.e. DDAVP)
    - Analgesia and Sedation – PRN included

Include the date and time infusions were initiated. Changes to infusion rates, including the times, are documented and may be updated verbally by the on-site coordinator. Dosages are calculated in mcg/kg/min or unit/min or mcg/min, i.e.: dosage per unit of time (not dosage per volume of fluid administered), i.e.: Levophed 0.5 mcg/kg/min (not Levophed 4 mg/250 mL).

17. Serology:
    The coordinator ensures all tests in TGLN's required infectious diseases screening panel are completed. See *Infectious Disease Testing – STAT Process Instruction, CPI-9-211*. The CSC ensures that the results of serology testing are documented. A copy is included in the TGLN donor chart. The coordinator ensures the lab is aware of the testing and confirms the estimated time to completion with the lab. Any pending serology tests are noted by the coordinator and may be considered as an EXD if the results will not be available prior to transplant.

    17.1 Pediatric Serology Testing:
    For pediatric donors, maternal serology testing is also required if the donor is 18 months old or less, or on any child who was breastfed within the last 12 months. See *Maternal Serology – SickKids Process Instruction, CPI-9-266*. However, the following exceptions apply:

    17.1.1 For donors ≤ 28 days old who have no obvious potential exposure to a blood-borne pathogen after birth, only the birth mother's STAT serology testing is required.

    17.1.2 For donors ≥ 29 days old, where NAT testing has already been completed on the infant donor, birth mother STAT serology testing is not required.

18. Past Medical & Social History Questionnaire:
    The S-OTD or designate will obtain required information from the potential donor's hospital medical record, family physician and NOK using the donor medical and social history questionnaire to guide data collection.

    Important: positive or unknown findings are shared with transplant programs and tissue banks. If the donor is 18 months old or less, and/or has been breast-fed in the past 12 months, a maternal donor medical and social history questionnaire must also be obtained and a maternal blood sample sent for appropriate STAT serology. If for any reason either one of these cannot be obtained, the organs would be considered under EXD provisions.

19. Hemodilution Calculation:
    The S-OTD or designate will perform a hemodilution calculation prior to drawing blood specimens for serology testing, to determine whether pre-dilution (stored) blood specimens should be obtained for testing. A calculation must be performed on every blood sample drawn for testing including non-stat testing. Blood product administration is documented by the S-OTD for the previous 48 hours in the donor management system. See *Hemodilution Calculation Process Instruction, CPI-9-210.* If an organ is offered from an out-of-province program, the hemodilution calculation is done by the offering program, and details of the calculation are given to the CSC.

20. Physical Assessment:
    The S-OTD or designate will conduct a thorough head-to-toe front-and-back assessment of the potential donor for any evidence of high-risk behavior, signs of malignancy, bacterial or viral infection, and trauma to the recovery site. Findings shall be documented, including line placement and the presence of tattoos, presence of piercings, scars (surgical or trauma), fractures, abrasions/lesions and/or rashes, signs of malignancies and infections. If there is consent for composite tissue, a detailed assessment of the site is completed on the *Limb Physical Assessment Form.* See Exhibit 5.
    The physical assessment shall be performed within 30 days of the scheduled date of the medical assistance in dying procedure or withdrawal of life-sustaining measures (WLSM).

21. Hemodynamics:
    The S-OTD notes any significant hypertensive or significant hypotensive episodes occurring since after consent for organ donation has been obtained, and documents the start time, duration, treatment and/or medications administered during this period. For most adults, normal blood pressure (BP) at rest is within the range of 100 - 130 millimeters mercury (mmHg) systolic and 60 - 80 mmHg diastolic. The following guidelines can be used for evaluating significant hypertensive and hypotensive episodes: hypertension can be defined as any systolic blood pressure above 180 sustained for more than 10 minutes and any diastolic blood pressure sustained above 110 for more than 10 minutes and significant hypotension can be defined as any sustained MAP below 60 for more than 20 minutes. Any episodes meeting this guideline need to be charted. Subsequent vital signs including central venous pressure (CVP)/right atrial pressure (RA), pulmonary artery pressure

(PAP), pulmonary capillary wedge pressure (PCWP), and cardiac index (CI) if available, urinary output (U/O) and intravenous (IV) intake are communicated to the (PRC) and documented every 6 hours and as needed.

22. General minimum testing information gathered for all donors will include**:**

- admission height
- admission weight
- ABO blood type and subtype if donor is A or AB (if subtyping is available)
- complete blood count (CBC) to include at minimum hemoglobin, hematocrit, white blood cell (WBC), platelet counts
- serum electrolytes, to include at minimum sodium and potassium
- serum creatinine
- chest x-ray (CXR) or chest CT (within a minimum of 30 days before organ retrieval)

Important: To confirm height and weight measurements, the donor shall be weighed using a bed scale and their height shall be measured using a measuring tape at the time of the physical assessment. If a bed scale is unavailable, then the weight will be specified as estimate.

23. Laboratory Data:
The S-OTD or designate records trends of all blood work and communicates them to the CSC on an ongoing basis. If the patient was transferred, include blood work results from the referring centre if available. The CSC will record ongoing updates every 6 hours (q6h). For all donor information which is transcribed from hospital charts, the S-OTD verifies the transcription before entering the data into the donor chart. Transcribed data should only be truncated if fields cannot fit the data in its entirety. See *Organ Specific Data Collection Process Instruction, CPI-9-215.*

24. Routine Cultures:
The S-OTD or designate will ensure that a full set of cultures (blood, urine, and sputum) have been sent. For follow-up reporting, see *Microbiology Testing Process Instruction, CPI-9-214*.

25. Heart Profile:
The S-OTD or designate will obtain a CXR, electrocardiogram and echocardiogram (if required). The S-OTD or designate ensures that a left ventricular (LV) ejection fraction/grade is included in the echocardiogram report. An angiogram will also be arranged if requested. In situations where an angiogram cannot be completed when requested, a CT coronary angiogram may be an acceptable alternative test. The S-OTD or designate will discuss transplant program acceptance of a CT coronary angiogram in place of an angiogram with the CSC prior to making arrangements for the test. Written reports are acceptable for allocation purposes; however, imaging recordings (discs or tapes) are encouraged if available.

26. Lung Profile:
    The on-site coordinator will document findings of current CXR, an admission CXR, or earlier report. Record the appearance and amount of secretions being suctioned, as well as the stat gram stain results from any sputum samples sent. A bronchoscopy is required if the patient's condition permits and a BAL for gram stain is collected. A sputum specimen shall be tested within 30 days before donation, or endotracheal aspirate, bronchial wash, or bronchoalveolar lavage (BAL) specimen for culture at the time of organ retrieval. Chest circumference is measured at the request of transplant programs. TLC is calculated. The S-OTD or designate will request that CXRs be repeated q12h (if possible) and hard copies retained for reading by the lung transplant team when they arrive for the surgical recovery, or made available to them electronically. Oxygen challenge testing is not typically completed for patients who donate after medical assistance in dying. For additional lung requirements, see *Organ Specific Data Collection Process Instruction, CPI-9-215.*

27. Blood Gases and Ventilator Settings:
    Current challenge arterial blood gases (ABGs) on 100% FiO_2 and PEEP 8 – 10 cm H_2O, 10 minutes after recruitment maneuvers (30 PEEP x 30 seconds) are completed q6h or as needed (prn). If recruitment maneuvers are not performed prior to ABGs or if patient is on a PEEP higher than 8 - 10, this information will be communicated to the CSC. Ventilator settings (including peak airway pressures) are documented q2-4h by the S-OTD and CSC, as applicable, and each time a ventilator change is made. For all donor information which is transcribed from hospital charts, the OTDC verifies the transcription before entering the data into the donor chart.

28. Abdominal Profile:
    The testing (abdominal CT and/or ultrasound), measurements and medication that make up the abdominal profile are dependent on which organs are being considered for donation. See *Organ Specific Data Collection Process Instruction, CPI-9-215* for organ specific requirements. All relevant information is collected and remains part of the permanent donor record.

29. Kidney/Pancreas Profile:
    The CSC will confirm that a creatinine clearance and glomerular filtration rate (GFR) has been auto-calculated in the donor chart if there is consent for kidney, kidney-pancreas, or isolated pancreas. For pediatric donors (< 18 years of age), the eGFR calculation that is auto-calculated by iTransplant should not be used. CSCs must communicate the serum creatinine to the kidney transplant program at the time of offer. Renal imaging (full report, including kidney size, cortical thickness and evidence of obstruction) will be done on all potential kidney donors. requirement, See *Organ Specific Data Collection Process Instruction, CPI-9-215* for organ specific requirements. For all donor information which is transcribed from hospital charts, the OTDC verifies the transcription before entering the data into the donor chart.

30. Urinalysis:

The on-site coordinator will request if there is consent for kidneys, kidney-pancreas, or isolated pancreas, that a complete urinalysis is documented. A urine dipstick result is satisfactory if urine random and microscopic (R&M) testing is unavailable. For all donor information which is transcribed from hospital charts, the OTDC verifies the transcription before entering the data into the donor chart.

31. Composite Tissue Profile:
    The coordinator will collect the height of parents if the donor and recipient are < 16 years of age and will complete a Fitzpatrick scale assessment. Additional test results to be recorded include capillary refill, Allen's test, Doppler ultrasound and an x-ray of the limb. Invasive lines will be repositioned to alternate limb, if needed. The patient identification band is also moved to an alternative limb.

32. Clinical Notes:
    Used by all coordinators to document all conversations with the referring centre, family, coroner, CMO or on-call designate, transplant physicians, etc. and any activities relevant to the donation.

33. Using the *TGLN Donor Case Closure Checklist*, the CSC makes sure all pertinent data has been collected. See Exhibit 4.

Part C: Tissue-Only Donation

The sections numbered below refer to data collection specific for tissue exclusive donation. Certain cases will require on-site coordinator support as assessed by the TC, CSC and S-OTD when a plan of care is developed or as per the Tissue Profile.

34. Referral:
    Once the initial referral/referral worksheet is complete, the coordinator proceeds to complete the assessment section of the chart.

35. Donor Suitability
    Suitability criteria will be established by the Medical Director-Tissue and will be in accordance with Health Canada/Canadian Standards Association (HC/CSA) and American Association of Tissue Banks (AATB) standards. Potential donors will be evaluated on an individual basis by chart review and physical assessment, noting the size of the donor, current medical status, and skin condition.

36. Review of Medical History
    A preliminary review of the donor's medical history must be conducted by TGLN personnel before recovery coordination can proceed. The TC or S-OTD will obtain required admission information from the potential donor's hospital medical record (EMS forms, physician's notes, ER and ICU flow sheets), including medications, white blood cell counts (WBCs), temperatures, cultures, and CXRs.

The TC or S-OTD will document if any intravenous (IV) fluids were given within the previous hour or if any blood products were given within the previous 48 hours. Additional information may be required from the attending and/or family physician, coroners, etc.

37. Disease Screening
    TGLN will obtain the following information from the NOK or physician as to whether any of the following applies, in which case the tissue will not be recovered:

    - evidence of significant active infection, specifically to communicable diseases. These include, but are not limited to: septicemia, viral disease (e.g., HIV, viral hepatitis, West Nile virus, rabies, etc.), human transmissible spongiform encephalopathies, untreated syphilis, clinically active tuberculosis, leprosy, or systemic mycosis;
    - risk factors for any communicable diseases
    - history of any other exclusionary diseases or conditions as outlined in the *General Tissue Donation Criteria and Contraindications Process Instruction, CPI-9-262.*

38. Coroner Involvement:
    Determine if the case requires the involvement of a coroner. If so, identify the name and phone number of the coroner and whether an autopsy is pending. Identify if there are any coroner's restrictions to the donation.

39. Outside Contacts:
    The donor's address and authorizing persons' information is documented. Additionally, family notification, body refrigeration and initial medical suitability to proceed are all documented.

40. Hemodilution Calculation:
    To determine whether pre-dilution (stored) blood specimens should be obtained for testing, the on-site TGLN coordinator or the TC/TRC (as applicable) will calculate the hemodilution factor prior to drawing blood specimens for serology testing. See *Hemodilution Calculation Process Instruction, CPI-9-210.* The TC/TRC will also document if the patient was transferred from another site; this includes date and time, if patient arrived via ambulance (including arrival date and time), plus any fluids administered at admission time. If information is collected by phone, the name of the healthcare professional providing the information relevant for the calculation will be recorded.

41. Donor Risk
    The NOK or designate will complete the relevant *Donor Risk Assessment Interview(s) with the TC or S-OTD.* Questions will be formed using *Health Canada's Safety of Human Cells, Tissues and Organs for Transplantation* (CTO) *Regulations* and AATB standards. Questions should be asked in order to evaluate whether a contraindication exists.

The TC or S-OTD will document the donor's name and the relationship of the donor to the interviewee. Separate questionnaires must be completed for each interview conducted. See *Medical & Social History – Tissue Process Instruction, CPI-9-261*.

42. Clinical Notes:
    All coordinators are to document all conversations with referring centre, coroner, CMO or on-call designate, relevant tissue banks and any activities relevant to the donation.

43. On acceptance of tissue(s) for transplant by tissue banks (as applicable), all relevant data is forwarded or faxed to the relevant tissue banks and recovery personnel by the TC/CSC or designate, as appropriate.

Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Assessment Form: Organ/Combined Organ & Tissue Donor	CSF-9-15	PRC	PRC	16 years
Assessment Form Tissue Donor	CSF-9-16	PRC	PRC	16 years
Limb Physical Assessment	CSF-9-18	PRC	PRC	16 years
Donor Medical & Social History Questionnaire	CSF-9-14	PRC	PRC	16 years
Triage Form	CSF-9-1	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
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:

- *Ontario Organ or Combined Organ and Tissue Donation Process Instruction, CPI-9-100*
- *Non-Ontario Organ Donation Process Instruction, CPI-9-101*
- *Donation Support Process Instruction, CPI-9-103*
- *Ontario Tissue Exclusive Referral Donation Process Instruction, CPI-9-160*
- *Coroner's Case Process Instruction, CPI-9-203*
- *Hemodilution Calculation Process Instruction, CPI-9-210*
- *Infectious Disease Testing – STAT Process Instruction, CPI-9-211*
- *Microbiology Testing Process Instruction, CPI-9-214*
- *Organ and Composite Tissue Specific Data Collection Process Instruction, CPI-9-215*
- *Exceptional Distribution Process Instruction, CPI-9-217*
- *Medical & Social History – Tissue Process Instruction, CPI-9-261*
- *General Tissue Donation Criteria and Contraindications, CPI-9-262*

- *Maternal Serology – SickKids, CPI-9-266*
- Health Canada: Safety of Human Cells, Tissues and Organs for Transplantation Regulations, Canada Gazette, Part II, Vol. 141, No. 13, June 27, 2007
- CAN/CSA-Z900.1: Cells, Tissues, and Organs for Transplantation and Assisted Reproduction: General Requirements, Canadian Standards Association
- CAN/CSA-Z900.2.3: Perfusable organs for transplantation, Canadian Standards Association
- Standards for Tissue Banking, American Association of Tissue Banks, United StatesD4.100, D4.220, D4.230, D4.300.

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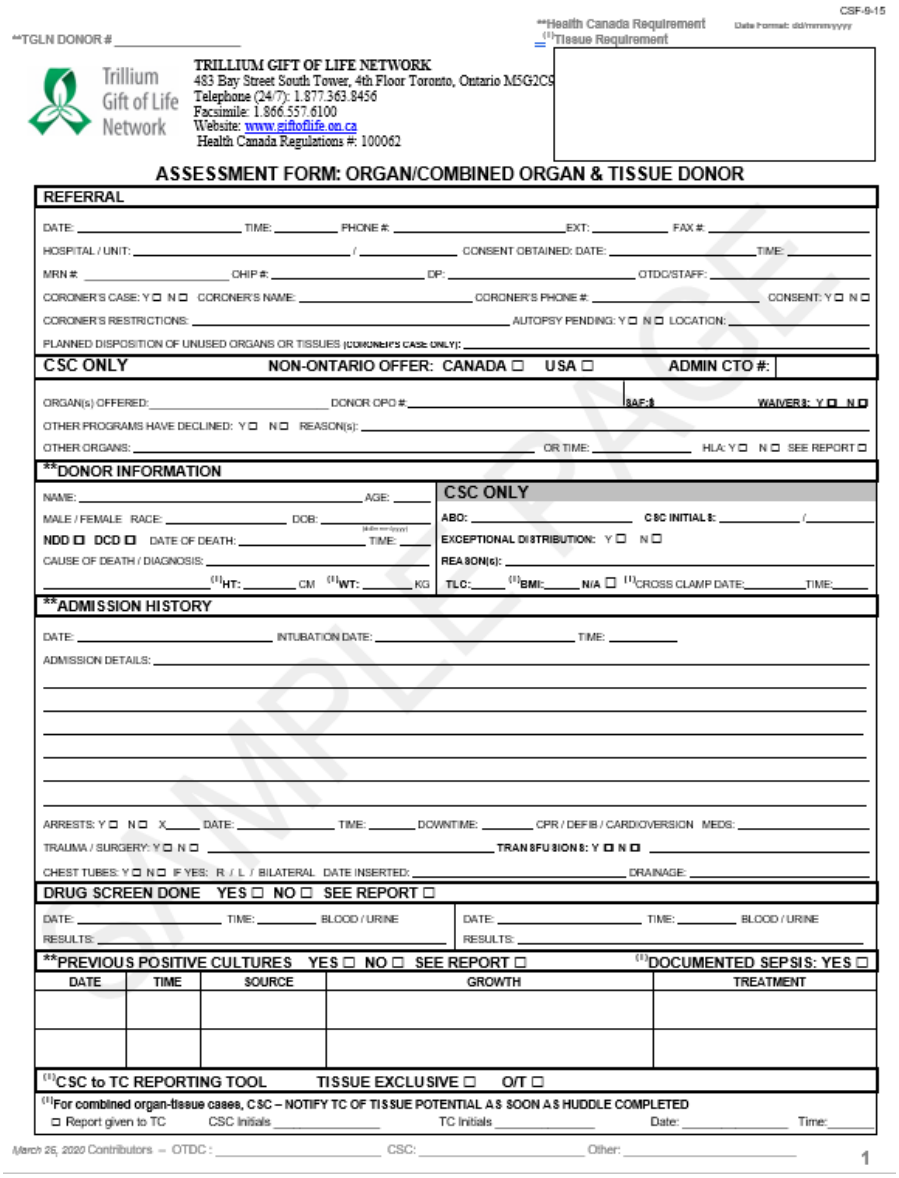
Exhibit 1: Assessment Form: Organ/Combined Organ & Tissue Donor
Page 1



CSF-9-15

**TGLN DONOR # _____

**Health Canada Requirement
(1)Tissue Requirement

Date Format: dd/mmm/yyyy

Trillium Gift of Life Network

TRILLIUM GIFT OF LIFE NETWORK
483 Bay Street South Tower, 4th Floor Toronto, Ontario M5G2C9
Telephone (24/7): 1.877.363.8456
Facsimile: 1.866.557.6100
Website: www.giftoflife.on.ca
Health Canada Regulations #: 100062

ASSESSMENT FORM: ORGAN/COMBINED ORGAN & TISSUE DONOR

REFERRAL

DATE: _____ TIME: _____ PHONE #: _____ EXT: _____ FAX #: _____

HOSPITAL / UNIT: _____ / _____ CONSENT OBTAINED: DATE: _____ TIME: _____

MRN #: _____ CHIP #: _____ DP: _____ OTDC/STAFF: _____

CORONER'S CASE: Y ☐ N ☐ CORONER'S NAME: _____ CORONER'S PHONE #: _____ CONSENT: Y ☐ N ☐

CORONER'S RESTRICTIONS: _____ AUTOPSY PENDING: Y ☐ N ☐ LOCATION: _____

PLANNED DISPOSITION OF UNUSED ORGANS OR TISSUES (CORONER'S CASE ONLY): _____

CSC ONLY NON-ONTARIO OFFER: CANADA ☐ USA ☐ ADMIN CTO #:

ORGAN(s) OFFERED: _____ DONOR OPO #: _____ $AF:$ WAIVERS: Y ☐ N ☐

OTHER PROGRAMS HAVE DECLINED: Y ☐ N ☐ REASON(s): _____

OTHER ORGANS: _____ OR TIME: _____ HLA: Y ☐ N ☐ SEE REPORT ☐

**DONOR INFORMATION

NAME: _____ AGE: _____

MALE / FEMALE RACE: _____ DOB: _____ (dd/mmm/yyyy)

NDD ☐ DCD ☐ DATE OF DEATH: _____ TIME: _____

CAUSE OF DEATH / DIAGNOSIS: _____

(1)HT: _____ CM (1)WT: _____ KG

CSC ONLY

ABO: _____ CSC INITIALS: _____ / _____

EXCEPTIONAL DISTRIBUTION: Y ☐ N ☐

REASON(s): _____

TLC: _____ (1)BMI: _____ N/A ☐ (1)CROSS CLAMP DATE: _____ TIME: _____

**ADMISSION HISTORY

DATE: _____ INTUBATION DATE: _____ TIME: _____

ADMISSION DETAILS: _____

ARRESTS: Y ☐ N ☐ X____ DATE: _____ TIME: _____ DOWNTIME: _____ CPR / DEFIB / CARDIOVERSION MEDS: _____

TRAUMA / SURGERY: Y ☐ N ☐ TRANSFUSIONS: Y ☐ N ☐ _____

CHEST TUBES: Y ☐ N ☐ IF YES: R / L / BILATERAL DATE INSERTED: _____ DRAINAGE: _____

DRUG SCREEN DONE YES ☐ NO ☐ SEE REPORT ☐

DATE: _____ TIME: _____ BLOOD / URINE
RESULTS: _____

DATE: _____ TIME: _____ BLOOD / URINE
RESULTS: _____

**PREVIOUS POSITIVE CULTURES YES ☐ NO ☐ SEE REPORT ☐ (1)DOCUMENTED SEPSIS: YES ☐

DATE	TIME	SOURCE	GROWTH	TREATMENT

(1)CSC to TC REPORTING TOOL TISSUE EXCLUSIVE ☐ O/T ☐

(1)For combined organ-tissue cases, CSC – NOTIFY TC OF TISSUE POTENTIAL AS SOON AS HUDDLE COMPLETED
☐ Report given to TC CSC Initials _____ TC Initials _____ Date: _____ Time: _____

March 25, 2020 Contributors – OTDC: _____ CSC: _____ Other: _____

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Clinical Process Instruction Manual

Donor Assessment – Combined Organ and Tissue Process Instruction

Exhibit 2: Assessment Form: Tissue Donor
Page 1

CSF-9-16

Trillium Gift of Life Network

Trillium Gift of Life Network
483 Bay Street South Tower, 4th Floor Toronto, Ontario M5G2C9
Telephone (24/7): 1.877.363.8456 Facsimile: 1.866.557.6100
Website: www.giftoflife.on.ca

Final Outcome:
❒Donor
❒Non-donor

Assessment Form – Tissue Donor

Referral (from database)

TGLN #: Date and Time: / / (day / month / year) @ hours
Hospital/floor: Ref'd From: Phone:
Coordinator(s): DP: Exceptions:
Donor Name: (Last Name, First Name) ❒Male ❒Female
MRN: OHIP #: Version Code:
DOB: / / Age: DOD: / / TOD: Date of Admission: / /

Case Coordination

Detailed COD: Fax #:
Current Patient Location: Time Transferred to Morgue: Family Notified: ❒No ❒Yes
Family Contact #1: Relationship: Phone:
Family Contact #2: Relationship: Phone:
Coroner's Case: ❒No ❒Yes Name of Coroner: Phone #:
Coroner Consent: ❒No ❒Yes Restrictions:
Autopsy Pending: ❒No ❒Yes Pathologist: Phone #:
Attending Physician: or ❒N/A R&T Phone #:
Family Physician: or ❒ N/A R&T Phone #:

Admission History

If VSA, time last seen/heard from: Intubated ❒No ❒Yes if Yes, Date: / / @ Hrs Duration:

Medical History

Details:

Diabetes: ❒No ❒Yes if Yes, ❒Type1 ❒Type 2 #Years: Meds:
Cancer: ❒No ❒Yes if Yes, type: Query sepsis: ❒No ❒Yes if Yes, Date:
Donor Height: ❒Actual ❒Estimated Donor Weight (current): ❒Actual ❒Estimated

Blood Work ❒N/A R&T				Temperature ❒N/A R&T		
Date	Time		WBC	Date	Time	°C
Blood Cultures	❒ No	❒ Yes	Date:	Results:		
Multi-Tissue Potential						
Sputum Cultures	❒ No	❒ Yes	Date:	Results:		
Urine Cultures	❒ No	❒ Yes	Date:	Results:		
CXR	❒ No	❒ Yes	Date:	Results:		
Antibiotics	❒ No	❒ Yes	From:	Type(s):		
Steroids	❒ No	❒ Yes	From:	Type(s):		

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Exhibit 3: Sample HSC Toxicology Form

SickKids
Paediatric Laboratory Medicine

TOXICOLOGY Requisition

TOXICOLOGY & THERAPEUTIC DRUG MONITORING Service
Atrium, Room 3642
170 Elizabeth Street
Toronto ON M5G 1X8 Canada
Tel: (416) 813-5906
Fax: (416) 813-6211

Urgency: ❑ STAT ❑ Routine

Patient Surname
First Name
History / Client #:
Ontario Health Card #:
Birthdate (YYYY-MM-DD):
Gender : ☐ Male ☐ Female

Referring Physician:
Referring Institution:
Address:

Phone Results to:
Tel #: *Fax #:*

CLINICAL INFORMATION

Toxidrome	Suspected Drugs, Mode and Time of Intake:
Please indicate how the patient presented:	
❑ SEDATIVE HYPNOTIC	Medications Given or Prescribed:
❑ STIMULANT	
❑ COMA - APNEA - SEIZURE	
❑ HALLUCINOGENIC	Brief Medical History:
❑ ANTICHOLINERGIC	
❑ UNKNOWN	

SPECIMEN AND REQUEST INFORMATION

❑ **BLOOD** (10 mL clotted required)	❑ **URINE** (10 mL required)	❑ **OTHER** _____ *(specify)*
Collected at:	Collected at:	Collected at:
____:____h_____-_____-_____	____:____h_____-_____-_____	____:____h_____-_____-_____
(hh:mm) (YYYY-MM-DD)	(hh:mm) (YYYY-MM-DD)	(hh:mm) (YYYY-MM-DD)
Your Specimen #	Your Specimen #	Your Specimen #
BLOOD TESTS REQUESTED:	**URINE TESTS REQUESTED:**	**OTHER TESTS REQUESTED** *(specify)*:
❑ **Volatile Screen** *(Ethanol, Methanol, Isopropanol, Acetone)*	❑ **Broad Spectrum Drug Screen** *(Excludes Barbiturates, Benzodiazepines & Cannabinoids)*	
❑ **Glycol Screen** *(Ethylene Glycol, Propylene Glycol)*	❑ **Benzodiazepine Screen**	
❑ **Barbiturates and Other Sedatives**	❑ **Barbiturate Screen**	
Analgesics	❑ **Cannabinoid Screen**	
❑ Acetaminophen	❑ **Ethanol Screen**	
❑ Ibuprofen	**Date Rape Drugs**	
❑ Salicylate	❑ Gamma Hydroxy Butyrate *(GHB)*	
Psychotropic Drugs	❑ Sensitive Benzodiazepine Screen	
❑ Benzodiazepine Screen	❑ **Other Tests**	
❑ Tryciclic Antidepressant Screen		
Date Rape Drugs		
❑ Gamma Hydroxy Butyrate *(GHB)*		
❑ **Other Tests**		
SickKids Lab #	SickKids Lab #	SickKids Lab #

Received Date and Time:

LABORATORY USE ONLY

DPLM Form #: OPL1000RTDMTOX-B/02, 2010-09-20

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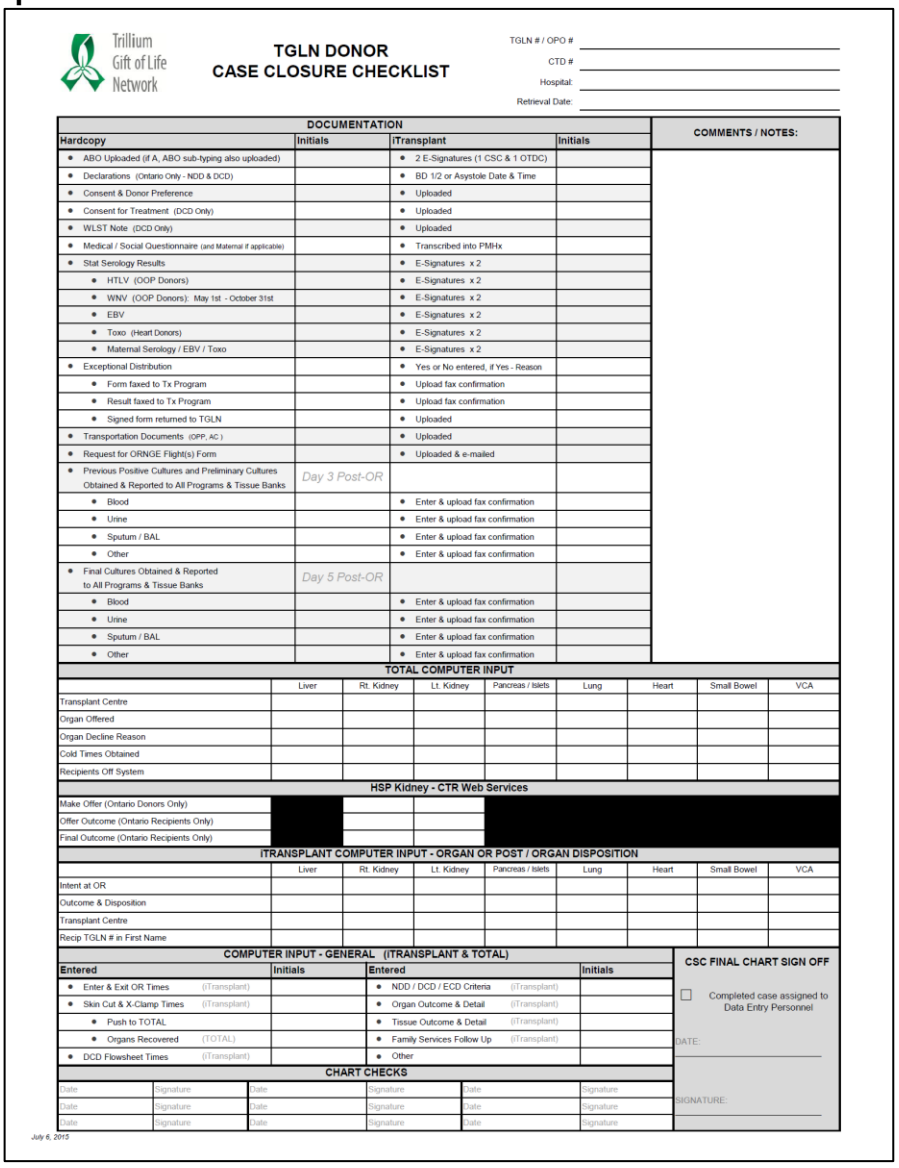
Exhibit 4: Sample TGLN Donor Case Closure Checklist



Trillium Gift of Life Network

TGLN DONOR CASE CLOSURE CHECKLIST

TGLN # / OPO #: _____
CTD #: _____
Hospital: _____
Retrieval Date: _____

DOCUMENTATION				COMMENTS / NOTES:
Hardcopy	**Initials**	**iTransplant**	**Initials**	
• ABO Uploaded (if A, ABO sub-typing also uploaded)		• 2 E-Signatures (1 CSC & 1 OTDC)		
• Declarations (Ontario Only - NDD & DCD)		• BD 1/2 or Asystole Date & Time		
• Consent & Donor Preference		• Uploaded		
• Consent for Treatment (DCD Only)		• Uploaded		
• WLST Note (DCD Only)		• Uploaded		
• Medical / Social Questionnaire (and Maternal if applicable)		• Transcribed into PMHx		
• Stat Serology Results		• E-Signatures x 2		
• HTLV (OOP Donors)		• E-Signatures x 2		
• WNV (OOP Donors): May 1st - October 31st		• E-Signatures x 2		
• EBV		• E-Signatures x 2		
• Toxo (Heart Donors)		• E-Signatures x 2		
• Maternal Serology / EBV / Toxo		• E-Signatures x 2		
• Exceptional Distribution		• Yes or No entered, if Yes - Reason		
• Form faxed to Tx Program		• Upload fax confirmation		
• Result faxed to Tx Program		• Upload fax confirmation		
• Signed form returned to TGLN		• Uploaded		
• Transportation Documents (OPP, AC)		• Uploaded		
• Request for ORNGE Flight(s) Form		• Uploaded & e-mailed		
• Previous Positive Cultures and Preliminary Cultures Obtained & Reported to All Programs & Tissue Banks	*Day 3 Post-OR*			
• Blood		• Enter & upload fax confirmation		
• Urine		• Enter & upload fax confirmation		
• Sputum / BAL		• Enter & upload fax confirmation		
• Other		• Enter & upload fax confirmation		
• Final Cultures Obtained & Reported to All Programs & Tissue Banks	*Day 5 Post-OR*			
• Blood		• Enter & upload fax confirmation		
• Urine		• Enter & upload fax confirmation		
• Sputum / BAL		• Enter & upload fax confirmation		
• Other		• Enter & upload fax confirmation		

TOTAL COMPUTER INPUT

	Liver	Rt. Kidney	Lt. Kidney	Pancreas / Islets	Lung	Heart	Small Bowel	VCA
Transplant Centre								
Organ Offered								
Organ Decline Reason								
Cold Times Obtained								
Recipients Off System								

HSP Kidney - CTR Web Services

Make Offer (Ontario Donors Only)	[redacted]			[redacted]
Offer Outcome (Ontario Recipients Only)				
Final Outcome (Ontario Recipients Only)				

iTRANSPLANT COMPUTER INPUT - ORGAN OR POST / ORGAN DISPOSITION

	Liver	Rt. Kidney	Lt. Kidney	Pancreas / Islets	Lung	Heart	Small Bowel	VCA
Intent at OR								
Outcome & Disposition								
Transplant Centre								
Recip TGLN # in First Name								

COMPUTER INPUT - GENERAL (iTRANSPLANT & TOTAL)

Entered	Initials	Entered	Initials
• Enter & Exit OR Times (iTransplant)		• NDD / DCD / ECD Criteria (iTransplant)	
• Skin Cut & X-Clamp Times (iTransplant)		• Organ Outcome & Detail (iTransplant)	
• Push to TOTAL		• Tissue Outcome & Detail (iTransplant)	
• Organs Recovered (TOTAL)		• Family Services Follow Up (iTransplant)	
• DCD Flowsheet Times (iTransplant)		• Other	

CHART CHECKS

Date	Signature	Date	Signature	Date	Signature
Date	Signature	Date	Signature	Date	Signature
Date	Signature	Date	Signature	Date	Signature

CSC FINAL CHART SIGN OFF

☐ Completed case assigned to Data Entry Personnel

DATE: _____

SIGNATURE: _____

July 6, 2015

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Exhibit 5: Limb Physical Assessment

Ontario Health

LIMB PHYSICAL ASSESSMENT CSF-9-18

TGLN DONOR # _____

LENGTH: Length of limb from the bony elbow tip to the bony prominence of the wrist: Left _____cm Right _____cm

RADIUS: Radius of wrist: Left _____cm Right _____cm

FITZPATRICK SCALE (please circle):

i. **Type I** – White; very fair, freckles, typical albino skin. Always burns, never tans.
ii. **Type II** – White; fair. Usually burns, tans with difficulty.
iii. **Type III** – Beige, very common. Sometimes mild burn, gradually tans to light brown.
iv. **Type IV** – Beige with brown tint, typical Mediterranean Caucasian skin. Rarely burns, tans with ease to a moderate brown.
v. **Type V** – Dark brown. Very rarely burns, tans very easily.
vi. **Type VI** – Black. Never burns, tans very easily, deeply pigmented.

Indicate any of the following on arm illustrations using letters below:

A – Abrasion	H – Tattoo
B – Bruise / Contusion	I – Fracture / Dislocation
C – Hematoma	K – Limb Trauma
D – Art Line	L – Piercing
E – TGLN Blood Collection	M – IV Puncture Site
F – Needle Entry Site	N – Peripheral IV Site
G – Scar	O – Other

PULSES PRESENT:

Brachial: Left: ☐ No ☐ Yes Right: ☐ No ☐ Yes
Radial: Left: ☐ No ☐ Yes Right: ☐ No ☐ Yes

CAPILLARY REFILL ASSESSMENT: Less than 2 sec? Left: ☐ No ☐ Yes Right: ☐ No ☐ Yes

PHOTOGRAPHS TAKEN AND UPLOADED: ☐ No ☐ Yes

MODIFIED ALLEN'S TEST COMPLETED: ☐ No ☐ Yes
If yes, attach the Modified Allen's Test with Doppler Worksheet

X-RAYS DONE: ☐ No ☐ Yes _PA and lateral view – hand, wrist and forearm)

DOMINANT HAND: ☐ Left ☐ Right

FUNCTIONAL LIMITATIONS: ☐ No ☐ Yes If yes, describe (including which limb) _____

Completed by: ___ (OTDC or qualified designate name) **Date:** ___/___/___ (DD MMM YYYY) @ ___Hrs (0000) **Signature:**

Arm assessment may only be completed prior to a negative COVID swab result if the Screening Tool indicates minimum risk.

For interest calls, OTDC assessment is required up to and including Capillary Refill Assessment for each limb. Complete form, including signature and date/time, then upload to iTransplant. This may be completed prior to VCA-specific consent.

Following VCA consent and confirmed interest, complete a new assessment and new assessment form once photographs, modified Allen's test and x-rays are completed. Sign and date/time the new form, then upload to iTransplant.

May 12, 2021

Clinical Process Instruction Manual

Donor Assessment – Combined Organ and Tissue Process Instruction

Exhibit 6 – Modified Allen's Test with Doppler - Worksheet

Ontario Health
Trillium Gift of Life Network

Modified Allen's Test with Doppler
VCA Bilateral Upper Limb Assessment Worksheet

CSF-9-246

TGLN#: _____

Date: _____ Time: _____

Instructions for physician completing assessment: Using a hand-held Doppler, occlude the radial artery with pressure at the wrist, and determine if there is a Doppler signal in the palm (flow coming in via the ulnar artery). Then, occlude the ulnar artery with pressure at the wrist, and determine if there is a Doppler signal in the palm (flow coming in via the radial artery). Repeat for both wrists.

LEFT WRIST	**YES**	**NO**
Left **ulnar** Doppler signal present	☐	☐
Left **radial** Doppler signal present	☐	☐
Comments:		

RIGHT WRIST	**YES**	**NO**
Right **ulnar** Doppler signal present	☐	☐
Right **radial** Doppler signal present	☐	☐
Comments:		

Physician who performed the assessment: _____

Signature: _____ Hospital: _____

May 12, 2021