Ontario Health
Trillium Gift of Life Network

Clinical Process Instruction Manual

Deceased Donor Exclusion Criteria and Suitability Screening Process Instruction

Policy:

Organ specific absolute and relative deceased donor exclusion criteria is developed in consultation with the Provincial organ specific working groups. The information is utilized by Trillium Gift of Life Network (TGLN) Coordinators to effectively screen potential organ donors for suitability to donate. Each organ specific deceased donor exclusion document includes Provincial absolute and relative donor exclusions for Death Determination by Neurologic Criteria (DNC) and Death Determination by Circulatory Criteria (DCC) donations as well as transplant program specific exclusions.

Organ specific absolute and relative deceased donor exclusion criteria are reviewed annually by the Provincial Heart, Lung, Kidney, Pancreas, Liver, Small Bowel, Liver/Bowel and Composite Tissue Specific Working Groups.

For the purposes of this process instruction, TGLN Coordinators are defined as Clinical Services Coordinators (CSC), Referral Triage Coordinators (RTC), Organ and Tissue Donation Coordinators (OTDC) and Clinical Responders (CR).

Process:

1. The TGLN Coordinator assesses deceased donor potential by obtaining organ specific assessment information from hospital staff. Information gathered during the assessment is reviewed against the organ specific *Provincial and Transplant Program Specific Exclusions* documents located on the Online Resource Centre (ORC). See a sample in Exhibit 1.

2. The presence of absolute exclusions during assessment exclude the specific organ being assessed. The presence of relative donor exclusions during assessment may require consultation with the Transplant Support Physician (TSP) or the Transplant Support Physican - Infectious Disease (TSP-ID) on-call for additional guidance in how to proceed. *Guidelines for Transplant Support Physician Consultation* (see Appendix 1) should be reviewed to determine whether a consultation is mandatory or recommended.

   2.1. If there are concerns about the result of a TSP consult, the TGLN Coordinator may escalate to the Chief Medical Officer (CMO) Transplant for a second opinion on the case.

3. During an emerging and/or declared outbreak of transmissible disease, TGLN in collaboration with the TSP-ID may develop and implement additional donor screening tools to assist in identifying and assessing donor risk level for transmission. See Exhibit 3 and Exhibit 4. Donation will not be facilitated for donors classified as being high-risk for transmission. The TSP-ID may advise Exceptional Distribution (ExD) be applied to donor risk levels identified by a screening tool as indeterminate or low as required. Refer to *CPI-9-217 for Exceptional Distribution process*.

3.1. If donor is suspected or confirmed to have *Influenza*, please refer to Appendix 2 prior to offering out organs.

4. Any consultation of the TSP or TSP-ID prior to consent should be for medical suitability only and should not include recommendations for medical management.

5. The TSP or TSP-ID may make medical management recommendations on consented donors including further testing or treatment of the potential donor.

   5.1. Any recommendations provided by the TSP or TSP-ID which result in significant changes in the management of a potential donor should be discussed with the most responsible physician (MRP).

6. All consultations with the TSP or TSP-ID should be documented in the *Organ Interest/TSP Calls* page and *Clinical Notes* of the donor chart.

7. Prior to contacting transplant programs regarding deceased donor organ offers, the TGLN Coordinator will review the *Provincial and Transplant Program Specific Exclusions* and will not offer organs when absolute exclusions are present.

Changes to *Provincial and Transplant Program Specific Exclusions*

8. When changes to the *Provincial and Transplant Program Specific Exclusions* are required, a Transplant Program must complete the *Program Specific Change Request* form and submit it to oh-tgln_clinicalservices@ontariohealth.ca. See Exhibit 2.

9. The Manager, PRC – Organ is responsible for sending *Provincial and Transplant Program Specific Exclusions* changes to the Quality Department or designate, who will update the document and post it on the ORC.

Records:

- No records.

References:

- Exceptional Distribution Process Instruction, CPI-9-217
- Provincial and Transplant Program Specific Exclusions on ORC

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Appendix 1: Guidelines for Transplant Support Physician Consultation

Background:
Trillium Gift of Life Network (TGLN) is responsible for deceased organ donation screening as the source establishment for donation in Ontario. Health Canada regulations require source establishments to conduct robust donor screening to ensure donated organs are safe for transplantation.
TGLN has partnered with two distinctive groups of physicians with expertise in transplantation for consultative services. Two Transplant Support Physicians Infectious diseases (TSP-ID) provide 24/7 on-call expert advice to prevent the transmission of infectious diseases from organ donors to transplant recipients. Six Transplant Support Physicians (TSP) provide on-call expert advice relating to donor suitability from the perspective of donor organ function and quality.

Purpose:
TSP consultative services are available to TGLN 24/7. Clinical coordinators are responsible for identifying and initiating a deceased organ donation screening consult by a TSP. The guidelines below outline when a deceased organ donation screening TSP consult is mandatory vs. recommended and what information is required for the consult:

Mandatory TSP Consult:

History of cancer
Essential: date of diagnosis and treatment(s), specific type of cancer including staging or grading, last follow-up and where
***Helpful*:** operative notes, pathology reports, treatment notes, follow-up notes and imaging reports
Usual course: low uptake with high mortality cancers

Concerns or evidence suggesting potential malignancy
***Essential*:** actual COD, history of malignancy, smoking history, presence/absence of recent symptoms concerning for potential malignancy
Helpful: recent/past imaging, feasibility of biopsy, specialty specific consultation including organ-specific physician opinion
***Usual course*:** low uptake with older donor/comorbidities vs. younger donor

History of genetic, autoimmune or bleeding disorders
***Essential*:** organs affected/function and laboratory results, recent/past specialty consultation/progress notes;

***Helpful*:** TSP review using UpToDate or internet resources; specialty specific consultation including organ specific physician opinion
***Usual course*:** usually requires expert opinion

Need for Exceptional Distribution is unclear as per *CPI-9-217 Exceptional Distribution*
***Essential*:** detailed review of risk concern in relation to Health Canada Exceptional Distribution guidelines
Helpful: recent/past imaging, recent/past laboratory testing related to risk concern
***Usual course*:** may be disagreement from transplant program on application of EXD – re-consult with TSP as requested by transplant programs

A surge in donation cases is identified and there is risk of losing a suitable organ as per *CPI 9-422 Surgical Recovery*
***Essential*:** CMO- Transplant involved in speaking with transplant program surgical directors when a surge is declared to help negotiate acceptable timelines/solutions to prevent organ loss

Recommended TSP Consult:

Marginal organ function
Essential: review of past medical history (hx of CV disease and poor organ function), admission history including attention to ischemic events, organ specific lab trends, trend in vital signs and organ specific testing/imaging results
***Helpful*:** previous description of pre-terminal organ function
***Usual course*:** younger donor results in higher likelihood of organ utilization. Older donors require pre-terminal evidence of normal organ function

Poor overall donor quality
***Essential*:** age, high BMI, multiple comorbidities especially vascular disease, significant smoking history, alcohol history
***Helpful*:** previous description of pre-terminal organ function
***Usual course*:** younger donor results in higher likelihood of organ utilization.

Trauma or anatomical defect in an organ
***Essential*:** current and previous imaging
***Helpful*:** evidence of pre-terminal organ function, organ-specific physician opinion
***Usual course*:** younger donor results in higher likelihood of organ utilization

Review need for further organ offers (after organ has been declined by 3 or more programs)
***Essential*:** review of previous TSP consult detail (if applicable), and reasons for decline of the organ
***Helpful*:** evidence of pre-terminal organ function
***Usual course*:** younger donor results in higher likelihood of organ utilization

Expedited recovery
***Essential*:** review of any increased risk concerns related to rapid organ allocation and recovery resource planning based on limited donor workup
***Helpful*:** TSP to be invited to participate in STAT Team Huddle if required as per *CPI-9-219 Expedited Recovery*

Mandatory TSP-ID Consult:

Positive blood cultures
***Essential*:** review of all culture reports from current admission including both positive and negative culture reports with dates and sensitivities if available and course of treatment (antibiotics with start and stop dates)
***Helpful*:** review of clinical status/presentation (including vital signs, labs, imaging, assessment findings)
***Usual course*:** start or change antibiotics and generally proceed

Evidence of endocarditis, meningitis, or encephalitis
***Essential*:** review of admission history, CSF culture reports, CSF cell count/differential (this is a must-have in cases of meningitis/encephalitis) and protein, blood cultures as above, and imaging reports that are suggestive of endocarditis, meningitis, or encephalitis
***Helpful*:** review of clinical status/presentation (including vital signs, labs, assessment findings, any CT/MRI head results if available)
***Usual course*:** CT chest / abdomen, antibiotics, disposition depends on organism

Signs of infection and/or sepsis NYD
***Essential*:** review of clinical status/presentation (including vital signs, labs, imaging, assessment findings), all culture reports from current admission and course of treatment
***Helpful*:** medical and social history questionnaire, imaging reports, consult/clinical notes
***Usual course*:** start antibiotics and generally proceed

Positive or indeterminate WNV test result (as per *CPI-9-211 Infectious Disease Testing-STAT*)
***Essential*:** if indeterminate - details of indeterminate result obtained from the laboratory technologist who performed the test and result of repeat WNV test performed at another Ontario lab. If positive – details of the positive test result. If indeterminate, email a copy of the report to TSP-ID
***Helpful*:** complete medical and social history, including travel history to assess potential exposure risk
***Usual course*:** If truly positive, then donor organs cannot be procured.

Positive, Indeterminate or Invalid COVID-19 test result
***Essential*:** Coronavirus (COVID-19) Donor Screening Tool (CSF-9-235) for the donor, details of the COVID-19 test (date/time performed, type of specimen, laboratory the test was performed at, cycle threshold, etc.)
***Helpful*:** details pertaining to the COVID status of the donor hospital/unit and any other facility the donor has been in
***Usual course*:** If positive, proceed at direction of TSP ID. If indeterminate or invalid, repeat test and proceed

History of Tuberculosis
***Essential*:** date of diagnosis and treatment(s)
***Helpful*:** microbiology reports, consult notes, treatment notes, follow-up notes and imaging reports
***Usual course*:** Can generally proceed with anti-TB medications for recipient if active TB ruled out

Recommended TSP-ID Consult:

Positive sputum cultures from potential lung donors
***Essential*:** review of all culture reports from current admission including both positive and negative culture reports with dates and sensitivities if available and course of treatment (antibiotics with start and stop dates)
***Helpful*:** review of clinical status/presentation (including vital signs, labs, imaging, CT chest results if available, assessment findings),
***Usual course*:** start or change antibiotics and generally proceed

Concerns related to communicable diseases or increased risk for transmission of communicable diseases

***Essential*:** admission history, including details that raise concern for increased risk of transmission of communicable diseases
***Helpful*:** medical and social history questionnaire, serology and/or NAT results (if available)
***Usual course*:** Additional testing of donor and/or recipient monitoring post-transplant

Request for NAT testing from a transplant program that does not meet TGLN criteria
***Essential*:** rationale for request from transplant program
***Helpful*:** medical and social history questionnaire, serology results (if available)
***Usual course*:** Generally, NAT not performed if TGLN criteria not met

Travel to or residency in a geographic region that is considered to be endemic for transmissible diseases (i.e. West Nile Virus, malaria, yellow fever, etc.)
***Essential*:** date(s) and location(s) of travel to and/or residency in the effected region, cause of death
***Helpful*:** medical and social history questionnaire
***Usual course*:** Additional testing of donor and/or recipient monitoring post-transplant

Recent travel to or residency in a geographic region under a level 2 or higher travel advisory for transmissible diseases (i.e. Zika, COVID19, etc.)
***Essential*:** date(s) and location(s) of travel to and/or residency in the effected region
***Helpful*:** medical and social history questionnaire
***Usual course*:** Additional testing of donor and/or recipient monitoring post-transplant

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Appendix 2: Guidelines Related to Organ Donation and Influenza

Guidelines Related to Organ Donation and Influenza (Includes H1N1, H3N2 and other community strains)*

* Based on Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO), Association of Organ Procurement Organization (AOPO), American Society of Transplantation and International Society of Heart and Lung Transplantation guidelines

Potential Donor →	(1) Confirmed diagnosis of Influenza	(2) Suspected or possible diagnosis of Influenza	(3) Previous history of Influenza	(4) Other- including those from ward or ICU where Influenza patients are present.
Description	Donor is diagnosed and *confirmed by testing*: i) In community, or ii) after admission to hospital iii) May be primary cause of death or may come to donation because of another condition.	Donor diagnosis suspected or possible but *not confirmed by testing*: i) in the community, or ii) after admission to hospital, or iii) Has symptoms suggestive of influenza	Donor has a history of illness but more than 10 days has passed since diagnosis and full clinical recovery.	Donation should proceed as normal.
Organs	Organs should not be used unless ≥ 5 days since its diagnosis and treatment with therapeutic doses of tamiflu or appropriate antiviral. Lungs and small bowel should normally not be donated.	1. If no history of treatment, organs should only be used after discussion with transplant physician and/or TGLN Tx ID. 2. If ≥ 5 days of tamiflu or appropriate antivirals, then organs may be used. 3. Lungs and small bowel should be used with caution.	Organ donation may proceed as regularly. If Influenza was present within two weeks, lungs and small bowel should be used with caution.	
Notes	1. Acceptance of organs at the discretion of the transplant physician. 2. Prophylaxis/ treatment for influenza should be administered to recipients. 3. Should discuss case with TGLN Tx ID.	1. NP swabs should be taken 2. Acceptance of organs at the discretion of the transplant physician. 3. Prophylaxis/treatment for Influenza should be administered to recipient pending donor swabs.	1. NP swabs should be taken. 2. Inform transplant program of patient's history of Influenza.	1. NP swabs should be taken. 2. Prophylaxis should be administered to any recipient of a donor proven to be positive.

* New emerging strains of Influenza such as H5N1 and H7N9 (bird flu viruses) are not included and should be discussed with Medical Director and TGLN Tx ID. Normally these donors would not be accepted under any condition.

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Exhibit 1: Provincial and Transplant Program Specific Exclusions - Sample

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Heart Deceased Donor Criteria
Provincial Heart/Lung Working Group

(Derived from 2010 ISHLT Guidelines for the Care of Heart Transplant Recipients & Organ Donor Management in Canada: Recommendations of the Forum on Medical Management to Optimize Donor Organ Potential, 2006)

ABSOLUTE DONOR EXCLUSION CRITERIA:

Absolute Donor Exclusion Criteria for Heart Transplantation

#	Factor	Criteria
1	Malignancy	• Donors with active cancer (donors receiving chemotherapy or radiation therapy or palliative cancer care within the last 5 years); excluding skin and primary brain tumours and prostate cancers (see below). • Donors with melanomas
2	Age	• DCD hearts are only considered for paediatric recipients and from donors < 1 years of age. • Hearts are not considered from any donor > 70 years of age
3	Infection / Communicable Diseases	• Positive HIV, HbsAg, HTLV-I/II test results • West Nile Virus (WNV), or recent exposure to WNV • Rabies or within the last 6 months bitten by an animal and treated as if animal was rabid • Documented fungal septicaemia • In general, infected donor hearts should not be used unless: ○ The donor infection is community acquired and donor death occurs within 96 hrs ○ Repeat blood cultures before organ procurement are negative ○ Pathogen-specific anti-microbial therapy is administered to the donor ○ Donor myocardial function is normal ○ There is no evidence of endocarditis by direct inspection of the heart
4	Cardiac Abnormalities	• Donors with pre-existing cardiac abnormalities: ○ The presence of intractable ventricular arrhythmias

RELATIVE DONOR EXCLUSION CRITERIA (HEART SPECIFIC):

Relative Donor Exclusion Criteria for Heart Transplantation

#	Factor	Criteria
1	Age	• Donor hearts younger than 45 years will have sufficient reserves to withstand the rigors of heart transplant even in the settings of relative prolonged ischemic time, recipient comorbidities and multiple previous recipient operations with hemodynamically destabilizing bleeding. • Hearts from donors between the ages of 45 to 55 years should probably be used when the projected ischemic time is < 4 hours and the potential recipient does not have comorbidities or surgical issues where anything else less than a robust donor heart performance could prove fatal • The use of donor hearts > 55 years should only be used if survival benefit in early HT survival due to transplantation of a heart with limited myocardial reserves
2	Drug Toxicities	• Donors with a history of non-intravenous cocaine use may be used as long as cardiac function is normal and LVH is absent • Donor hearts from carbon monoxide poisoning may be used provided: ○ EKG and echocardiogram are normal; ○ Minimal elevation in cardiac markers;

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Exhibit 2: Program Specific Change Request Form - Sample

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DONOR EXCLUSION CRITERIA
PROGRAM SPECIFIC CHANGE REQUEST

Transplant programs are to complete this form to notify the Provincial Resource Centre (PRC) of any changes to transplant site specific donor exclusion criteria. Once the document is received, the PRC will update the transplant site specific exclusions section of the relevant Donor Exclusion Criteria document and make offers accordingly.

Please complete this form and send the request to ClinicalServices@GiftofLife.on.ca. Please note that all change requests must be confirmed and signed by the transplant centre medical director.

Date: **Transplant Hospital:** Choose Transplant Hospit

Person Submitting Request: **Contact #:**

Change applicable to the following donor organ:

☐ Kidney ☐ Kidney/Pancreas ☐ Liver ☐ Heart
☐ Lung ☐ Small Bowel ☐ All Organs ☐ Other, specify:

Type of Change required:

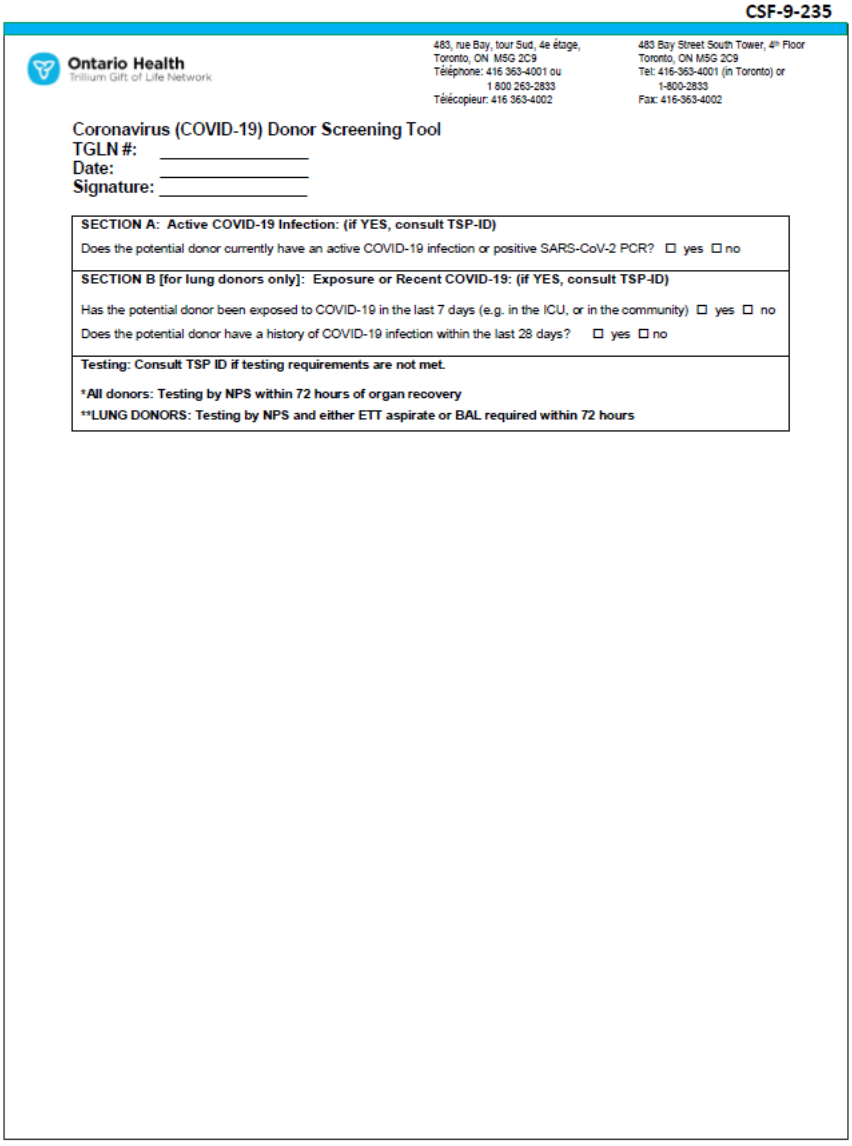
TRANSPLANT CENTRE MEDICAL DIRECTOR

I am confirming that the requested change is accurate:

Name: **Signature:**

August 12, 2014

Exhibit 3: Infectious Disease donor screening tool



CSF-9-235

Ontario Health
Trillium Gift of Life Network

483, rue Bay, tour Sud, 4e étage,
Toronto, ON M5G 2C9
Téléphone: 416 363-4001 ou
1 800 263-2833
Télécopieur: 416 363-4002

483 Bay Street South Tower, 4th Floor
Toronto, ON M5G 2C9
Tel: 416-363-4001 (in Toronto) or
1-800-2833
Fax: 416-363-4002

Coronavirus (COVID-19) Donor Screening Tool
TGLN #: _____
Date: _____
Signature: _____

SECTION A: Active COVID-19 Infection: (if YES, consult TSP-ID)
Does the potential donor currently have an active COVID-19 infection or positive SARS-CoV-2 PCR? ☐ yes ☐ no

SECTION B [for lung donors only]: Exposure or Recent COVID-19: (if YES, consult TSP-ID)
Has the potential donor been exposed to COVID-19 in the last 7 days (e.g. in the ICU, or in the community) ☐ yes ☐ no
Does the potential donor have a history of COVID-19 infection within the last 28 days? ☐ yes ☐ no

Testing: Consult TSP ID if testing requirements are not met.
***All donors: Testing by NPS within 72 hours of organ recovery**
****LUNG DONORS: Testing by NPS and either ETT aspirate or BAL required within 72 hours**

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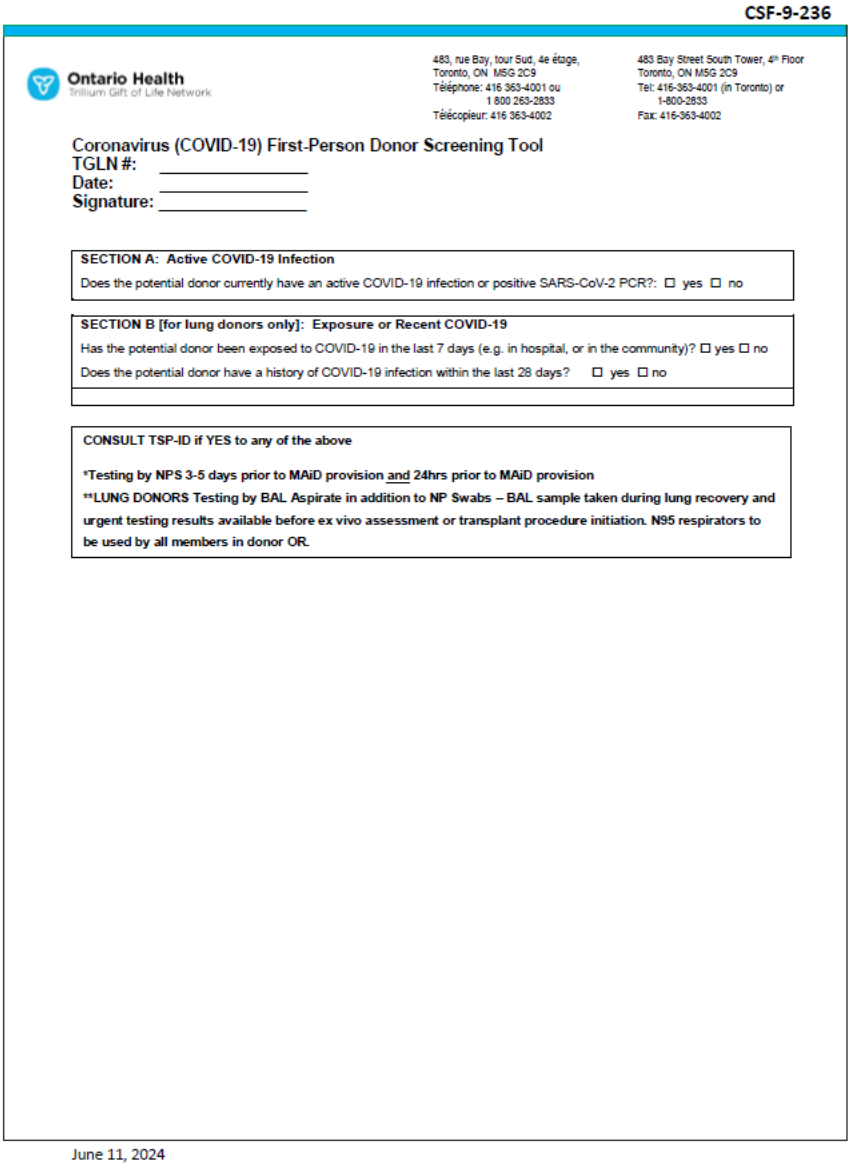
Exhibit 4: First Person Infectious Disease donor screening tool



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1-800-2833
Fax: 416-363-4002

Coronavirus (COVID-19) First-Person Donor Screening Tool
TGLN #: _____
Date: _____
Signature: _____

SECTION A: Active COVID-19 Infection

Does the potential donor currently have an active COVID-19 infection or positive SARS-CoV-2 PCR?: ☐ yes ☐ no

SECTION B [for lung donors only]: Exposure or Recent COVID-19

Has the potential donor been exposed to COVID-19 in the last 7 days (e.g. in hospital, or in the community)? ☐ yes ☐ no

Does the potential donor have a history of COVID-19 infection within the last 28 days? ☐ yes ☐ no

CONSULT TSP-ID if YES to any of the above

***Testing by NPS 3-5 days prior to MAiD provision and 24hrs prior to MAiD provision**

****LUNG DONORS Testing by BAL Aspirate in addition to NP Swabs – BAL sample taken during lung recovery and urgent testing results available before ex vivo assessment or transplant procedure initiation. N95 respirators to be used by all members in donor OR.**

June 11, 2024