



## Clinical Process Instruction Manual

### Non-Perfused Organ Donation (NPOD) Process Instruction

#### Policy:

Donation after Death Determination by Circulatory Criteria (DCC) refers to the process of solid organ donation after cardio-circulatory death, rather than neurologic criteria. Non-Perfused Organ Donation (NPOD) refers to DCC situations where a patient suffers unanticipated cardiac arrest and resuscitation is unsuccessful. No reperfusion intervention will occur after unsuccessful resuscitation in NPOD donors.

Trillium Gift of Life Network (TGLN) accepts notifications for potential DCC and NPOD donation. Assessment of eligibility for organ donation in these situations is permissible under the TGLN Act. Potential NPOD donors must meet specific predefined criteria, including time of cardiac arrest to estimate warm ischemic time.

#### Process:

#### NPOD Assessment

1. The healthcare professional (HCP) or TGLN coordinator may refer to the “NPOD Flowchart” to ensure the necessary steps are taken to facilitate the NPOD referral and donation process. See Exhibit 1: *NPOD Flowchart*.
2. The designated Registered Nurse (RN) will identify the referral as a potential NPOD candidate for patients that meet the criteria for NPOD. See Appendix 1: *NPOD Referral Criteria for Screening*.
3. The referral is transferred to the Referral Triage Coordinator (RTC) or Clinical Services Coordinator (CSC) and registered in the TGLN database.
  - 3.1. If the HCP does not immediately identify the referral as a potential NPOD, and the Tissue Coordinator (TC) begins entering the patient details in the donor management system, upon identification of the referral as an NPOD, the TC will:
    - 3.1.1. Ensure the Referral Type is entered as “Organ and Tissue (OT)”
    - 3.1.2. Ensure the Donor Type is entered “Non-Perfused Organ Donor”
    - 3.1.3. Save the referral
    - 3.1.4. Provide the TGLN # to the HCP
    - 3.1.5. Provide the TGLN # to the RTC/CSC
    - 3.1.6. Transfer the call to the RTC/CSC for further assessment.
4. The RTC/CSC will:
  - 4.1. Ensure the Referral Type is entered as “Organ and Tissue (OT)”



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- 4.2. Ensure the Donor Type is entered “Non-Perfused Organ Donor”
5. The RTC or CSC completes a preliminary assessment for NPOD eligibility and documents this assessment in the chart. See Appendix 1: *NPOD Referral Criteria for Screening*.
6. If eligibility or suitability for NPOD is ruled out at any point in the process, the referral is transferred to the Tissue Lead Coordinator (Lead TC) for tissue suitability evaluation.
7. The RTC or CSC will document the estimated time of arrest, duration of arrest and time of death. The three-hour time limit for NPOD organ recovery will commence from the time of death.
8. The RTC or CSC contacts the NPOD lung physician or designate to assess interest and the ability to recover based on resources available.
9. If the NPOD lung physician or designate expresses interest in proceeding and there are concerns regarding available resources to facilitate an NPOD donation, or the patient or next of kin are not identified, the RTC or CSC will contact the Manager-On-Call (MOC). A dispatch plan for consent, onsite hospital support and surgical recovery will be discussed.
  - 9.1. When assessing resources for surgical recovery, any Surgical Recovery Coordinator (SRC) that has already been assigned to a consented case with a pending donor OR (Operating Room) should not be re-assigned for NPOD donation. The RTC or CSC will contact the MOC to explore other options for surgical recovery support before shutting down the case.
10. If proceeding with NPOD, the RTC or CSC will contact and inform the RN. If NPOD cannot proceed due to resources, the RTC or CSC will contact and inform the RN and the NPOD lung physician or designate who had expressed interest.
11. The RTC or CSC completes a look up of the Registered Consent Decision if the OHIP number is available and documents it in the chart.

### Consent & Dispatch

12. The RTC or CSC will determine who will approach the family for NPOD consent and/or provide onsite hospital support.
  - 12.1. If there is an Organ and Tissue Donation Coordinator (OTDC) onsite at the donor hospital, the OTDC will be notified to approach the family for NPOD consent and provide hospital support.
  - 12.2. In the event there is not an OTDC onsite, the RTC or CSC will utilize the GTA OTDC on-call schedule and assign the first available on-call OTDC to do an NPOD telephone approach.



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The CSC or RTC will simultaneously dispatch the second available GTA on-call OTDC to the donor hospital.

12.3. In the event, there is no GTA OTDC on-call available to do an NPOD telephone approach, the RTC or CSC will utilize in the following order.

12.3.1 Clinical Responder (CR) in the GTA

12.3.2 A Near North on-call OTDC/CR

12.3.3 OTDC/CR in any region

13. The RTC or CSC will notify the SRC of the potential NPOD referral and dispatch if appropriate (e.g., Donation Preference - Transplant or family mention of donation).

14. The OTDC/CR will discuss the approach plan with the designated RN. The next-of-kin (NOK) must be informed of the death. If NOK are en route to hospital, it is preferable to approach once they are onsite if timing allows. If the NOK do not have any immediate plans to travel onsite, a telephone approach may be completed. If the designated RN does not feel an approach is appropriate, a huddle may be arranged with the MOC, OTDC/CR, RTC or CSC and designated RN to determine how to proceed.

15. If NPOD consent is obtained, the OTDC/CR asks the NOK to confirm the suitability screening information obtained earlier from the designated RN during the NPOD referral. See Appendix 1: *NPOD Referral Criteria for Screening*. If consent has not been obtained at 90 minutes, a call should be made to the MOC to provide an update on timing and to discuss next steps.

15.1. A case may still proceed if consent is delayed if the following conditions are met:

15.1.1. Lungs have been inflated;

15.1.2. Lung transplant surgeon agrees with the delay;

15.1.3. Lung transplant recovery surgeon has been dispatched anticipating consent

16. OTDC/CR must also request consent for Multi-Tissue donation if time permits. At minimum, OTDC/CR must obtain verbal consent for multi-tissue donation to permit drawing blood samples for multi-tissue donation.

17. If exclusionary criteria for NPOD is confirmed during the discussion with NOK, the OTDC/CR will inform the designated RN, the RTC or CSC, and the NOK that NPOD donation is no longer possible.

17.1. If NPOD donation is excluded, the OTDC/CR will approach for multi-tissue consent. If consent for multi-tissue donation is obtained, the OTDC/CR will complete the consent and Medical Social Questionnaire with NOK.



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- 17.2. The OTDC/CR will notify the RTC or CSC of the NOK's decision regarding multi-tissue donation.
- 17.3. If there is consent for multi-tissue donation, the RTC/CSC will update the Lead TC.

#### Coroner Process

18. In the event of a known or suspected Coroner's case, verbal permission from the Coroner for NPOD lung donation and multi-tissue donation is required before proceeding. The Coroner must give permission for the removal of the lungs from the body cavity, drawing of bloods for testing, and multi-tissue donation.
19. The Most Responsible Physician (MRP) will contact the Coroner to advise of the potential NPOD lung and multi-tissue donation. If consent for donation is given by the NOK, the OTDC/CR will speak directly with the Coroner to obtain permission for NPOD. If the Coroner denies permission for NPOD, the case is closed.
20. If the Coroner gives permission to proceed with NPOD donation, the OTDC/CR will document this in the chart and on the *Coroner/Forensic Pathologist Permission Form*.
21. In the event the Coroner does not give permission for NPOD, the Coroner escalation process should be followed. See *Coroner's Case, CPI-9-203*.

#### Dispatch & Recovery

22. After consent, the RTC transfers the case to the CSC. The CSC will ensure the following notifications regarding consent are made:
- NPOD lung physician or designate and Multi-Organ Transplant Coordinator (MOTC)
    - CSC will advise that Exceptional Distribution (ExD) is being applied to this donor due to incomplete donor testing, in addition to any other ExD reasons identified as per *Exceptional Distribution Process Instruction, CPI-9-217*.  
Note: All NPOD donors will be ExD due to missing mandatory test results, including, but not limited to, serum electrolytes, creatinine and CBC results.
  - SRC
  - MOC
23. If the SRC has not already been dispatched, the SRC will travel directly to the donor hospital. The SRC will provide updates to the CSC if any unexpected delays should occur that may affect a delayed start to the donor OR.



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24. The CSC will notify and arrange for the lung recovery fellows for travel to the donor site.
25. The CSC will notify the OTDC/CR of the dispatch plan and provide estimated arrival times of the recovery teams.
26. If a second OTDC/CR was dispatched to provide onsite hospital support, the OTDC/CR who obtained consent will transfer the case to the OTDC/CR upon arrival to the donor hospital.
27. Immediately following consent, the following steps will be completed by the OTDC/CR:
  - 27.1. Verify the consent form and NPOD progress note with the MRP and attach a copy to the donor chart.
  - 27.2. Ensure a stat or rapid PCR COVID-19 test, if available, has been completed and negative.
  - 27.3. Notify the OR of the pending recovery and to book the OR as an "A-Case".
  - 27.4. Request the appropriate blood be drawn for HLA/serology testing, blood cultures, ABO (if not already done), the Coroner if it is a Coroner's case and multi-tissue donation.
    - 27.4.1. Blood tubes for lung donation and the Coroner, and those for multi-tissue donation will be kept in separate bags.
    - 27.4.2. The blood tubes may be kept with the body and transported with the organs and/or tissue recovery teams to the appropriate laboratories after the recovery is complete, or left with the body for the Coroner.
    - 27.4.3. Ensure the serology requisition indicates the sample as cadaveric/post mortem blood.
    - 27.4.4. Ensure that a hemodilution calculation is completed.
    - 27.4.5. In the event blood cannot be drawn, the OTDC/CR will request that the recovery team draw blood in the OR during the recovery.
    - 27.4.6. In the event that there is difficulty drawing blood during the recovery, bloods for the purposes for lung donation should be drawn before bloods for multi-tissue donation.
  - 27.5. Ensure patient is intubated and recruitment maneuver initiated, then place patient on positive pressure circuit with 20 cm H<sub>2</sub>O CPAP with room air or FiO<sub>2</sub> less than 50% oxygen.
  - 27.6. Ensure patient is placed in the prone position.
  - 27.7. Obtain hardcopy of ABO, actual height and estimated weight which must be sent to the PRC and added to the donor chart.
28. In conjunction with the OTDC/CR, the following steps will be completed by the designated RN and MRP:
  - 28.1. Obtain the NPOD cart to be brought bedside.



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- 28.2. Complete NPOD progress note and ensure Exhibit 2: Confirmation of Death Determination by Circulatory Criteria (DCC) for the Purpose of Uncontrolled Organ Donation: Non-Perfused Organ Donation (NPOD) Draw blood for HLA/serology testing, blood cultures, ABO (if not already done), the Coroner (if it is a Coroner's case), and multi-tissue donation. In the event the blood draw is unsuccessful, blood may be drawn in the OR.
- 28.3. Ensure the donor is intubated.
- 28.4. Initiate a lung recruitment maneuver, then place on circuit with 20 cm H<sub>2</sub>O CPAP with room air or FiO<sub>2</sub> less than 50% oxygen.
- 28.5. Place patient in the prone position.
- 28.6. Ensure the body is transferred to the OR in the prone position for prepping and draping.
- 28.7. Ensure that the ER team is available to assist in unproning the patient once in the OR.
29. The OTDC/CR is responsible for obtaining a hardcopy of the ABO. See *ABO Compatibility Process Instruction, CPI 9-300*.
  - 29.1. If the result is available prior to the start of the donor OR, the CSC verifies the ABO and communicates the result to the NPOD lung physician.
  - 29.2. Best efforts should be made to obtain the donor ABO prior to the donor OR. If the donor ABO is unavailable prior to the start of the donor OR, the organ recovery may still proceed.
  - 29.3. If the NPOD lung physician confirms and selects a suitable recipient, the CSC will immediately notify the MOTC and provide the name of the selected recipient.
30. Once onsite, the SRC and lung recovery fellows initiate the set-up of the OR.
31. The SRC will locate the blood tubes and requisitions required for HLA & Serology testing if already drawn.
32. Prior to skin-cut, a rapid huddle must occur with the MOC, OTDC/CR, CSC and SRC. See *Appendix 2: Rapid Huddle Guidelines*.
33. The recovery of the organ begins in the OR. Recovery of the lungs must occur within 180 minutes from the time of death.
34. The SRC will ensure that a BAL is collected for rapid COVID-19 testing, as per *CPI-9-211 Infectious Disease Testing – STAT Process Instruction*.
35. If not already complete, the following steps may be completed by the OTDC/CR when the donor is in the OR.





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- complete the physical assessment

Note: If the COVID-19 test result is unknown, proper PPE, including N-95 mask precautions, must be utilized.

- completes *CSF-9-235 Emerging Infectious Disease Screening Tool (COVID-19)* with the NOK
- complete the full Medical Social Questionnaire with the NOK
- complete the hemodilution calculation

36. The OTDC/CR notifies the CSC once the Medical Social Questionnaire is completed. The CSC will transcribe positive and unknown answers into the donor chart.

#### Tissue Donation

37. The OTDC/CR will approach for multi-tissue consent after approaching for NPOD consent. This can be verbal consent, and the written consent for multi-tissue is obtained at the same time as the written consent for lung donation.

38. When the written consent for lungs and multi-tissue is obtained, the OTDC/CR will attach it to the donor chart.

39. The RTC or CSC assigns the NPOD case to the Lead TC. The Lead TC will be responsible for:

- Confirming the OTDC/CR has placed the *Hold Body Form – Consented Tissue Donor in the patient's chart*
- completing a tissue assessment over the telephone with the OTDC/CR
- confirming with the OTDC/CR that bloods for multi-tissue donation have been drawn as per *Appendix 3: Blood Specimen Collection for NPOD Tissue Donation*, and their location
- offering tissues to the tissue banks as per *Accepting and Offering Tissue, CPI-9-360*.
- if it is a Coroner's case, ensuring the OTDC/CR has obtained coroner permission for all consented tissues
- booking an OR for multi-tissue recovery with the OTDC/CR if the OTDC/CR is still onsite, otherwise the Lead TC must coordinate with the OR staff

#### Post-Recovery Responsibilities

40. When the recovery is complete and the lungs are en route to the transplant hospital, the CSC provides the estimated time for organ arrival to the NPOD lung physician and MOTC.



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41. The SRC arranges transportation of the organ and the lung recovery fellows to the transplant hospital per *Transportation Coordination Process Instruction, CPI-9-404*. NPOD lungs are placed on Ex-Vivo Lung Perfusion (EVLP) and evaluated for potential transplant.
42. The SRC will drop off the BAL for rapid COVID-19 testing, HLA & serology samples to the appropriate laboratories.
43. The CSC will confirm with the microbiology, HLA and serology labs that the samples were received and obtains an estimated completion time for results.
44. When the microbiology, HLA and serology labs complete required testing, they will notify the CSC of the results.
  - 44.1. If the BAL for rapid COVID-19 testing is positive, the CSC must notify the following:
    - MOTC
    - OTDC/CR
    - SRC
    - MOC
    - Lead TC
  - 44.2. Lead TC must notify all the recovery staff who have been assigned to the NPOD case as recovery is no longer required.
45. Prior to running a lung allocation, the CSC will verify if all the necessary information is complete:
  - hardcopy of ABO
  - actual height and estimated weight
  - hardcopy of consent
  - HLA typing and VXM result
  - Exceptional Distribution
  - physical examination
  - hemodilution
  - medical social questionnaire
  - serology results (if available)
  - Negative COVID-19 result (if available)





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46. The CSC relays the outstanding information to the NPOD lung physician, noting any reasons for Exceptional Distribution.
47. If the lungs are deemed suitable for transplantation, the CSC will contact the NPOD lung physician or designate to obtain:
  - chest x-ray (if not yet completed)
  - arterial blood gases
  - bronchoscopy (if not yet completed)
48. The CSC will transcribe this information to the donor chart.
49. The CSC will also confirm if a BAL culture sample was collected and sent for testing.

### Inventory of Supplies Held at the Hospital

50. If NPOD case supplies were utilized and need to be re-stocked, the SRC will arrange to have a new stock of NPOD supplies sent to the hospital on the next business day.
51. Prior to shipping a new stock of NPOD supplies, the SRC will contact the OTDC or designate about the shipment.
52. The OTDC or designate will keep an inventory of the NPOD supplies at their hospital site including lot numbers and expiry dates. The inventory log will be updated monthly and as needed when new supplies are received. See Exhibit 3: *NPOD Lung Inventory List*.
53. The OTDC or designate is responsible for notifying the SRC group via e-mail if there are any damaged or expired supplies in need of replacement. Upon discovery, the OTDC or designate ensures damaged or expired supplies are discarded.



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#### Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
NPOD Lung Inventory List	CSF-9-119	Hospital Program	Hospital Program	16 years

#### References:

- *Coroner's Case Process Instruction, CPI-9-203*
- *Infectious Disease Testing – STAT Process Instruction, CPI-9-211*
- *Exceptional Distribution Process Instruction, CPI-9-217*
- *ABO Compatibility Process Instruction, CPI-9-300*
- *Transportation Coordination Process Instruction, CPI-9-404*



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#### Appendix 1: NPOD Referral Criteria for Screening

##### Donor Exclusions:

- ≥ 65 years of age
- Active COVID-19 positive
- If arrest was unwitnessed - time last seen alive was > 1 hour prior to being found VSA
- Smoking history > 20 pack-years
- COPD
- Active cancer or history of cancer in the last 5 years (except basal cell carcinoma skin cancer)
- Death related to asthma or COVID-19
- Major chest trauma leading to massive hemothorax

##### Documentation required:

- Time resuscitation started?
- Time of death?
- Intubated or supraglottic airway?
- If yes, has patient been placed on continuous positive pressure circuit with room air (no tidal volume)?
- Is it a Coroner's Case?
- Is death a homicide or criminal investigation?
- Previous bypass surgery?
- Current or recent chest infections?
- Brief medical history:
- Has a stat or rapid PCR for COVID-19 been done on the patient?
- OHIP number (if known):
- ABO (if known):
- Height & weight (if known):
- Is family onsite and aware of death?



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#### Appendix 2: NPOD Rapid Huddle Guidelines

Huddle team members:

- Manager-on-call (MOC)
- CSC/TL
- RTC
- OTDC/CR
- SRC (if available)
- Designated RN (if available)

The following must be reviewed prior to NPOD Recovery:

- When was Time of Death?
- COVID-19 considerations: Stat or rapid PCR COVID-19 test result? TSP-ID call needed?
- Has the patient been declared x2?
- Is there any coroner involvement?
- Confirm Consent
- Medical Social History Questionnaire – any areas of concern or reason for ExD?
- Confirm ETT in place with PEEP
- Has serology & HLA been drawn? Do all blood tubes have valid expiry dates?
- Has the case been assigned to Tissue Team Lead, and have tissue bloods been drawn?
- Have recovery teams arrived at hospital/what is their estimated time of arrival?
- Is the OR booked and are there any concerns?
- Have blood cultures been drawn?



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#### Appendix 3: Blood Specimen Collection for NPOD Tissue Donation

##### Blood Specimen Collection for NPOD Tissue Donation

Blood Tubes (in draw order)	
Green (30ml)	Aerobic Blood Culture
Orange (40ml)	Anaerobic Blood Culture
Gold (5ml)	Clot Activator
Red (6ml)	Non-Additive (i.e. Nothing)
Yellow (8.5ml)	ACD
Pink (6ml)	EDTA
Lavender (6ml)	EDTA

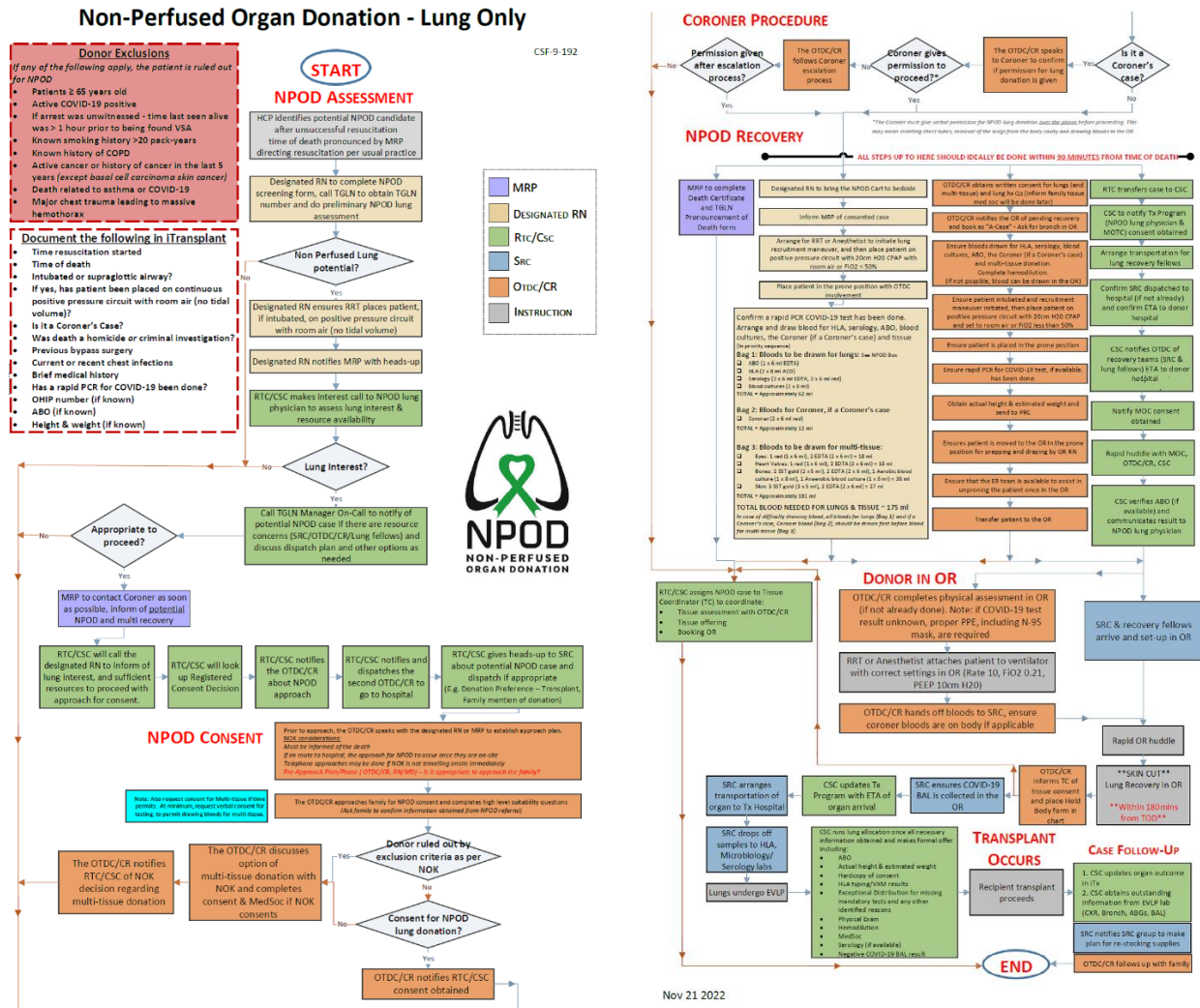
TISSUE BANK	BLOOD DRAW REQUIRMENTS	TOTAL BLOOD	
Eye Bank of Canada (EBC - eyes)	1 Red Top 1x6ml = 6ml 2 EDTA 2x6ml = 12ml	6ml + 12ml = 18ml TOTAL	If all Tissues consented, OTDC to collect:  2 Red Top 8 EDTA 5 SST Gold 1 Aerobic Blood Culture* <u>1 Anaerobic Blood Culture</u> =101ml TOTAL
Hospital for Sick Children (HSC - heart valves)	1 Red Top 1x6ml = 6ml 2 EDTA 2x6ml = 12ml	6ml + 12ml = 18ml TOTAL	
Sunnybrook Health Sciences Centre (SBK - skin)	3 Gold 3x5ml = 15ml 2 EDTA 2x6ml = 12ml	15ml + 12ml = 27ml TOTAL	
Mt. Sinai Allograft Technologies (MSAT - bones)	2 SST Gold Top 2x5ml = 10ml 2 EDTA 2x6ml = 12ml 1 Aerobic Blood Culture 1x 8ml = 8ml *Fill Green cap Aerobic blood culture bottle first* 1 Anaerobic Blood Culture 1x8ml =8ml	10ml + 12 ml + 16ml = 38ml TOTAL	
Lake Superior Centre for Regenerative Medicine (RMD - bones and skin)	2 SST Top 2x5ml = 10ml 2 EDTA 2x6ml = 12ml	10ml + 12ml = 22ml TOTAL	



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### Exhibit 1: NPOD Flowchart – Lung Only







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Exhibit 2: Confirmation of Death Determination by Circulatory Criteria (DCC) for the Purpose of Uncontrolled Organ Donation: Non-Perfused Organ Donation (NPOD)

Patient ID

CSF-9-223

**Confirmation of Death Determination by Circulatory Criteria (DCC) for the Purposes of Uncontrolled Organ Donation: Non-Perfused Organ Donation (NPOD)**  
Place in chart and fax to 416-214-7797

<b>TGLN ID:</b>			
<b>Confirmation of Death Determination by Circulatory Criteria</b>			
<b>Section 1: Observation Period</b>			
Following termination of resuscitation, a 10-minute observation period begins at the onset of <del>apnea</del> asystole, and pulselessness for Non-Perfused Organ Donation (NPOD) following DCC as noted on page 2.			
<b>Date/time of the start of the observation period</b>	(DD-MM-YY):	(00:00):	
<b>Section 2: Time of Death</b>			
For the purposes of post-mortem transplant, the legal time of death shall be determined at the end of the observation period.			
This patient fulfills the criteria for DCC as noted on page 2			<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Date/time of death</b>	(DD-MM-YY):	(00:00):	
First Clinician (print):	Signature:		
Second Clinician (print):	Signature:		
<b>Coroner Involvement</b>			
<i>Office of the Chief Coroner: (416) 314-4100</i>			
* if required, please inform the Dispatcher this is an "Emergent NPOD Lung Donation"			
As per the <i>Coroners Act</i> , does this patient require a coroner investigation?			<input type="checkbox"/> Yes <input type="checkbox"/> No
Coroner (Name):			
<b>Permission obtained for donation?</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No	(DD-MM-YY):	(00:00)
Coroner Restrictions/Instructions:			

Both physicians must be available to attend to the patient until the organ flush has commenced. The Ontario Health (TGLN) Coordinator will inform the physicians once organ flush has begun and relieve them of their duty.

November 29, 2023



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CSF-9-119

#### NPOD LUNG INVENTORY LIST

Date inventory checked \_\_\_\_\_ (dd/mmm/yyyy) By \_\_\_\_\_

##### Lung Recovery Bag

Item	Lot#	Exp Date dd/mmm/yyyy	Qty Req'd	Qty On Hand	Notes
Y-Tubing					
Tourniquet Kits					
3M –Steri-Drapes Bags					
Pour Spouts					
Specimen Containers Sterile 90ml					
Specimen Trap (BAL) 40ml					
Slip Tip Syringe 30ml					
TA 30 Stapler					
TA 30 Reload					
Venous Return Cannulas (12,16,20,24, 32)					
Microbiology Reqs					
Packing Slips					
Biohazard Bags					
Yellow ACD Vacutainers					
Pink/Lav Vacutainers					
Red Vacutainers					