

## Clinical Process Instruction Manual

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### Non-Ontario Organ Donation Process Instruction

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#### Policy:

All offers of organs (referrals) to Ontario transplant programs from the U.S. and other Canadian provinces are received and managed by Trillium Gift of Life Network (TGLN). In the case of referrals from the U.S., TGLN may also discuss offering of organs to other Organ Procurement Organizations (OPOs) outside of Ontario.

Referrals from Canadian OPOs are accepted without exchange of funds (transportation costs excepted). When a deceased donor organ is offered to TGLN by a U.S. OPO, the OPO charges a Standard Acquisition Fee (SAF) for cost recovery. The Ontario Ministry of Health (MOH) provides a managed fund to Trillium Gift of Life Network (TGLN) to reimburse transplant hospitals for the SAFs paid to U.S. OPOs for organs accepted and transplanted in Ontario.

#### Process:

1. All incoming referral calls are directed as appropriate. For Ontario referrals, refer to *Ontario Organ or Combined Organ and Tissue Donation Process Instruction, CPI-9-100*. If the caller is from outside of Ontario, including the U.S., with an organ donor referral, the call is immediately transferred to a Clinical Services Coordinator (CSC). In the event that the CSC is not available to take the referral, a Referral Triage Coordinator (RTC) may take the initial referral information.
  - 1.1. For Canadian OPOs participating in the interprovincial electronic sharing of donor data between donor management systems, the offering OPO may send the offer directly to the TGLN donor management system, via a one-time donor data transfer of donor information. All offers of this nature must be accompanied by a phone call by the offering OPO to the PRC to advise of the offer. The CSC will review the donor information and donor documents in the TGLN donor management system, and ensure all required information is provided or requested, as outlined in steps 3 to 12. New and updated donor attachments can be received via subsequent pushes from the OPOs donor management system. All other updates to donor information must be communicated by phone/email/fax between the OPOs.
2. For all other organ offers, the CSC/RTC will create an Out of Province donor record with the referral information provided.
3. The CSC will ask the OPO to send a hard copy of the donor ABO results. Upon receipt and verification of the hard copy of the ABO results, the CSC will upload the ABO result to the donor record. See *ABO Compatibility Process Instruction, CPI-9-300*.

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4. The CSC will ask the OPO to send a hard copy of the donor HLA results, with the exception of when the offer is for a Highly Sensitized Patient (HSP) kidney or High Status Heart (HSH) recipient. See *Organ Donor Allocation - Highly Sensitized Program (HSP)*, CPI-9-310 and *Organ Donor Allocation - Interprovincial Organ Sharing (IPOS) Hearts*, CPI-9-316. Upon receipt and verification of the hard copy of the HLA results by two CSC's/RTC's, the CSC will ensure the donor TGLN# is on the hard copy, upload the HLA result to the donor record and will contact the appropriate HLA lab regarding the need for HLA typing data entry. See *Histocompatibility Testing Process Instruction*, CPI-9-216.
5. The CSC will obtain documentation of consent to donate from the referring program.
6. The CSC will arrange for the OPO to forward the completed serology results, medical/social history, and donor assessment to the Provincial Resource Centre (PRC). See *Donor Assessment Process Instruction*, CPI-9-208. If any required testing is incomplete, the CSC requests to have the tests completed by the OPO or documents the reason the testing will not be completed in the clinical notes.
7. The CSC should assess whether Exceptional Distribution provisions are applicable and ensure transplant programs are made aware. See *Exceptional Distribution Process Instruction*, CPI-9-217.
8. The CSC will enter the serology results into the donor management system. Two CSCs will complete independent double checks of the transcribed serology results, as per *Infectious Disease Testing – STAT Process Instruction*, CPI-9-211.
9. The CSC will upload the redacted source OPO serology report to the Organ Allocation and Transplant System (OATS).
10. For donors  $\leq$  18 months, or breast fed in the last 12 months, where maternal serology was completed, the maternal serology and past medical/social history must be provided as hard copy as well.
11. For referrals originating from a Canadian province other than Ontario, the CSC will determine whether the offer is for a specific Ontario recipient who is eligible for interprovincial organ sharing, or open to any Ontario recipient. Furthermore, the CSC will:
  - 11.1. Determine whether the organ has been declined by other eligible programs and the reason for decline (e.g. size incompatibility or other suitability factors).
  - 11.2. Determine whether local recovery of the offered organ is available.
  - 11.3. Generate the appropriate allocation list(s) for the organ(s) being offered. See *Coordination of Organ Placement – All Organs Process Instruction*, CPI-9-302.

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- 11.4. Consult allocation list(s) generated using Ontario organ specific algorithm(s) to identify the appropriate recipient and discuss with the referring program.
  - 11.5. Contact Ontario transplant programs with offers for Ontario recipients, and refer any offers needing to be made to non-Ontario recipients appearing on the allocation back to the referring Canadian OPO.
12. If an Ontario transplant program requests translation of a non-English donor document or report, the CSC will facilitate a real time consultation between the transplant program and a translator using a third-party translating service.
13. If the offered organ is accepted by an Ontario transplant program, and local recovery is confirmed, the CSC will verify the type of flush and preservation solutions that the OPO intends to use during organ recovery and packaging. The CSC will communicate this to the Ontario transplant program and confirm with the Ontario transplant program that the solutions are acceptable.
- 13.1. If the organ offer is for a kidney, the CSC will ask if the local recovery surgeon has the ability to place the kidney on a LifePort™ kidney pump. The CSC will relay the outcome of this conversation to the accepting Ontario transplant program, and make the necessary arrangements, as required.

### Referrals from the U.S

14. For referrals originating from the U.S., the CSC will determine why the organ has not been allocated to a U.S. recipient. The CSC will:
  - 14.1. Establish if the offer is a primary or back-up offer. If the offer is a back-up, the CSC will ask the U.S. program to call back when the offer becomes primary.
  - 14.2. Inquire about any limitations on the offer (i.e. Is the organ being offered to any Canadian program or to specific locations only?). If the offer is limited to Ontario programs only, the CSC will document the rationale for not offering nationally (i.e. time/distance).
14. For lung offers received from Lung Bioengineering in the U.S, the CSC will refer to the steps outlined in Appendix 1: Toronto Lung Bioengineering Pathway.
15. The CSC will not request information regarding the SAF fee and will not be involved in any discussions regarding the SAF fee.
  - 15.1. Any opportunities to safely import a potentially life-saving organ from a U.S. OPO for an Ontario patient should be taken. Transplant hospitals should not set limits on the amount of SAFs payable to U.S. OPOs for organs.

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- 15.2. TGLN and University Health Network (UHN) have agreed to set a limit for the reimbursement of lungs imported from the U.S. The upper limits have been set at 20,000 CAD for Single and 35,000 CAD for Double. A policy memo regarding these limits has been shared with U.S. OPOs. Any concerns or disagreement that arise during case coordination relating to this memo will be addressed after the fact and should not prohibit a potential life-saving organ transplant.
16. The CSC inquires about the waiver type and communicates it to the accepting program during the organ offer. Waiver types typically include:
- Full waiver: the SAF is not charged if the organ is recovered, transported to Ontario, and declined prior to transplant (i.e. lungs are declined after a period of time on ex-vivo);
  - Partial waiver: the SAF is charged once the organ is recovered and transported to Ontario, regardless of whether the organ is transplanted or not;
  - No waiver: the SAF is charged once the organ is accepted and arrangements for a recovery OR are made.
17. The CSC generates the appropriate allocation list(s) for the organ(s) being offered using the Ontario organ specific allocation algorithm(s) identify the allocation plan. See *Coordination of Organ Placement – All Organs Process Instruction, CPI-9-302*.
18. The CSC will contact Ontario transplant programs with offers for Ontario recipients, and refer any offers needing to be made to non-Ontario recipients appearing on the allocation back to the referring U.S. OPO.
19. In the event an Ontario transplant program identifies that the waiver status may prevent acceptance of the organ offer, the CSC will contact the Manager on-call (MOC) and will make arrangements for a discussion with an appropriate contact at the U.S. OPO making the offer. The CSC will notify the Ontario transplant program about the escalation.
20. The MOC will contact the U.S. OPO and advocate for a waiver status that is acceptable to the Ontario transplant program highlighting:
- 20.1. Not-for-profit publicly funded healthcare system in Ontario
  - 20.2. Limited funding to cover costs associated with U.S. organ imports
  - 20.3. Ethical dilemma of not placing an otherwise suitable organ
  - 20.4. Ontario provides full waivers for organs exported to the U.S.
21. In the event the MOC is unable to reach consensus regarding the waiver status with the U.S. OPO, the MOC will ask for the contact information for the U.S. OPO's Senior Administrator on-call (AOC) or Chief Financial Officer (CFO). The MOC will escalate the issue to the TGLN AOC and will provide the contact information for the U.S. OPO's AOC and/or CFO.

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#### Donation After Death Determination by Circulatory Criteria (DCC)

22. For OOP DCC organ offers, the CSC will ask about hospital or OPO policies that may limit waiting and observation time periods to asystole after withdrawal of life support. The CSC will communicate any OOP hospital or OPO specific time restrictions to the Ontario transplant program at the time of offer.
23. The CSC will obtain a desired dose for ante mortem Heparin from the accepting transplant program, and relay the heparin dose request to the OOP coordinator.
- 23.1. If there are concerns with the requested amount, or the administration of heparin, the CSC will relay all information to the transplant program for consideration.

#### Pediatric Donors

24. If an organ(s) is accepted from a pediatric donor by an Ontario transplant program, the CSC will confirm with the recovery surgeon if any special equipment is needed and communicate this to the SRC. The SRC is responsible for packing any special equipment if readily available required for the organ recovery prior to departure.

#### Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Donor Chart	—	PRC	PRC	16 years

#### References:

- *Ontario Organ or Combined Organ and Tissue Donation Process Instruction, CPI-9-100*
- *Infectious Disease Testing – STAT Process Instruction, CPI-9-211*
- *Organ and Composite Tissue Specific Data Collection Process Instruction, CPI-9-215*



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- *Exceptional Distribution Process Instruction, CPI-9-217*
- *ABO Compatibility Process Instruction, CPI-9-300*
- *Coordination of Organ Placement – All Organs Process Instruction, CPI-9-302*
- *Organ Donor Allocation - Highly Sensitized Program (HSP), CPI-9-310*
- *Organ Donor Allocation - Interprovincial Organ Sharing (IPOS) Hearts, CPI-9-316*
- *Independent Double Check and Electronic Sign Off – ABO and Serology Process, CPI-9-220*

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#### Appendix 1: Toronto Lung Bioengineering Pathway (Lung Bioengineering)

##### Toronto Lung Referral Pathway (Lung Bioengineering)

