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## Clinical Process Instruction Manual

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### Organ Donor Allocation – Highly Sensitized Program Process Instruction

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#### Policy:

Provincial donation and transplantation programs/agencies who participate in the national Highly Sensitized Program (HSP) registry have committed to offering kidneys to highly sensitized patients who are matched through HSP registry matching policies.

In accordance with provincial algorithms, Trillium Gift of Life Network (TGLN) facilitates the placement of organs donated to and within Ontario. TGLN will attempt to allocate all consented organs. The national HSP registry is managed by Canadian Blood Services through its Canadian Transplant Registry (CTR) and identifies transplant opportunities for patients who are waiting for a kidney or kidney/pancreas transplant that are highly sensitized to Human Leukocyte Antigens (HLA). To be eligible for the HSP registry, patients must have a cumulative Calculated Panel Reactive Antibodies (cPRA) > 95%.

To ensure fair and equitable distribution of organs, inter-provincial thresholds exist for the export of HSP kidneys only. Ontario's export threshold is 12.

All local transplant programs and agencies have two hours from the time the offer is made, to accept or decline the HSP offer for an HSP recipient.

TGLN coordinators will ensure that all donor information exchanged with local transplant programs and/or other agencies during the offering and/or recovery process will be shared appropriately as outlined in *Disclosure of Donor and Recipient Personal Information to External Stakeholders during Offering, Acceptance and Recovery CPI-9-1306*.

For the purposes of this instruction, TGLN coordinators are defined as Clinical Services Coordinators (CSC) and Organ and Tissue Donation Coordinators (OTDC).

Note: Donor Management System information fields for types of donors by determination of death have not been updated. For the purposes of Donor Management System *Death determination by neurologic criteria* (DNC) equals NDD; and *Death determination by circulatory criteria* (DCC) equals DCD.

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#### Procedure:

#### Ontario Donor

1. The CSC “pushes” donor information from the Donor Management System to the TGLN organ allocation and transplant system so that HLA labs can enter results. Information required by the Donor Management System for the push to the organ allocation and transplant system includes:
  - gender
  - height
  - weight
  - ECD (Yes or No) on Donor Information Page
  - DCD or NDD on Donor Information Page
2. The HLA lab will notify the CSC when the HLA typing results have been completed and entered into the organ allocation and transplant system.
3. The CSC will review the consent uploaded in the Donor Management System by the OTDC to ensure that kidney consent has been given, and confirms kidney consent is entered into the Donor Management System on the Authorization screen (required for a kidney offer through CTR for HSP). The CSC will ensure that this information has been pushed to the organ allocation and transplant system.
4. The CSC will ensure that the donor ABO has been entered into the Donor Management System and electronically signed. The CSC will ensure that this information has been pushed to the organ allocation and transplant system.
5. The CSC will ensure donor stat serology has been completed and is entered into the Donor Management System (required for a kidney offer through CTR for HSP). The CSC will ensure that this information has been pushed to the organ allocation and transplant system.
6. The OTDC updates the Donor Management System with all details required to make a kidney offer including:
  - Medical/Social History
  - Admission and recent lab values

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- All required donor information as outlined in *Donor Assessment Process Instruction, CPI 9-208*.
7. The CSC reviews all donor information and determines if the donor meets Exceptional Distribution (ExD) criteria. The CSC may consult the Transplant Support Physician (TSP) on call for clarification as needed.
  8. The CSC enters the following into the Organ Pre-OR Tab in the Donor Management System:
    - 8.1. CSC confirms if donor is an Extended Criteria Donor (ECD) and updates the ECD field on Donor Information screen in the Donor Management System.
    - 8.2. CSC confirms if donor is ExD and updates the ExD box on Donor Information screen in the Donor Management System.
  9. The CSC will “re-push” donor information to OATS for the purposes of allocation.
  10. Required donor data elements for national HSP kidney matching will now have been sent to CTR.
  11. A six digit national ID # for the donor will now have been generated in the organ allocation and transplant system. The CSC will locate the national ID # in the organ allocation and transplant system in the “Referral Information” section of the Donor Profile.

#### ***Generating an Allocation for HSP (Ontario Donor)***

12. Prior to running the provincial kidney allocation the CSC will ensure a six digit national ID # has been generated and is visible in the organ allocation and transplant system.
13. After running the local kidney allocation, the CSC will run the Provincial Kidney Allocation to check if there are any HSP recipients. HSP recipients will only appear on the Provincial Allocation report.
14. If the donor has two kidneys available for allocation, the CSC offers one kidney from the local allocation and the second kidney from the provincial allocation. HSP recipients will only appear on the Provincial Kidney Allocation report in the section titled “HSP Patient Identified by CTR”.
15. The following Exceptions should be noted:

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- 15.1 Medically urgent Ontario recipients will take priority over HSP recipients.
- 15.2 If there is only one transplantable kidney, or if the kidneys are to be offered enbloc/doubles, the kidney(s) will be allocated to a local recipient first.
- 15.3 Kidney-Pancreas cluster recipients will still be offered an HSP kidney even if the pancreas is not eligible for allocation (i.e. medically unsuitable).
- 15.4 Once the national HSP export threshold for Ontario is met, TGLN will only export an HSP kidney when the following criteria are met:
  - 15.4.1 HSP recipient cPRA = 100%
  - AND**
  - 15.4.2 No multi-organ, pediatric, kidney-pancreas, list exchange/previous living donor, cPRA  $\geq$ 95% Ontario recipients appear on the Ontario kidney allocation.
- 15.5 If an HSP kidney offer will lead to loss of a whole organ for transplant in Ontario (i.e., no pancreas only or liver only recipients on allocation), a discussion with the Chief Medical Officer (CMO) – Transplant will need to occur to determine if an HSP offer should be made.
- 15.6 Any request to deviate from the allocation should be discussed with the CMO-Transplant.

#### ***Offering Process for Ontario HSP Recipients***

16. For Ontario HSP recipients appearing on the allocation, the CSC will contact the Ontario transplant program for that recipient to make the offer.

Note: If the virtual crossmatch (VXM) indicates a possible allele specific donor-specific anti-HLA antibody (DSA), the CSC will contact the recipient HLA lab prior to offering, as outlined in *CPI-9-313 Organ Allocation*.

17. Once the program listing the HSP recipient has accepted or declined the kidney offer, the CSC or transplant program updates the organ allocation and transplant system and the CSC documents this in the clinical notes in the Donor Management System.

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#### *Offering Process for Out-of-Province HSP Recipients*

18. For OOP HSP recipients appearing on the allocation, the CSC contacts the respective Organ Procurement Organization (OPO) to make the offer.
19. The CSC will make the HSP offer(s) to the HSP recipient in the organ allocation and transplant system on the allocation screen.
20. Once the offer(s) is entered into the organ allocation and transplant system, the information is transmitted to CTR where the OOP OPO will now be able to view donor HLA and recipient HLA information on their local system or CTR directly.
21. If the OOP OPO has questions about donor HLA typing or VXM for the HSP recipient, the CSC will make arrangements for the Ontario donor HLA laboratory to speak with the HSP recipient OPO's HLA laboratory to discuss directly.
22. The OOP OPO will notify the CSC with the offer acceptance or decline.
23. The CSC updates the organ allocation and transplant system and the Donor Management System to indicate acceptance or decline reasons.

#### **Out-of-Province Donor**

24. The OOP OPO will contact the Provincial Resource Centre (PRC) with the HSP Kidney offer. The CSC requests the necessary donor information to register the OOP Donor HSP offer in the Donor Management System. Information for registration in the Donor Management System requires:
  - hardcopy of ABO
  - hardcopy of serology
  - hardcopy of consent
  - hardcopy of donor HLA typing
25. The CSC obtains the six digit national Donor ID # from the OOP OPO and enters this into the "Referral Worksheet" in the Donor Management System in the following format: *CTD000123*.

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26. The CSC will review the hardcopy of the consent to ensure that kidney consent has been given and enters this into the Donor Management System.
27. The CSC will ensure donor stat serology has been uploaded and entered into the Donor Management System. A second CSC will verify the donor stat serology and must co-sign the results.
28. The CSC updates the Donor Management System with all details required to make a kidney offer including:
  - medical/social History
  - admission and recent lab values
  - all required donor information as outlined in *Donor Assessment Process Instruction CPI 9-208*.
29. The CSC enters the following into the Organ Pre-OR Tab in the Donor Management System:
  - 29.1. For OOP HSP Offers, the ECD box must be set to “N/A” in the Donor Management System
  - 29.2. If the donor is ExD, the CSC updates the ExD box in the Donor Management System
30. The CSC “pushes” donor information from the Donor Management System to the organ allocation and transplant system. Information required by the Donor Management System for push to the organ allocation and transplant system so that an HSP recipient allocation can be generated:
  - ABO (electronically signed)
  - height
  - weight
  - age
  - date of birth
  - ECD (N/A) on Donor Information Page
  - DCD or NDD on Donor Information Page

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- kidney consent
- serology
- national ID # in the following format: *CTD000123*

#### ***Generating an Allocation for HSP (OOP Donor)***

31. Prior to running the provincial kidney allocation, the CSC will ensure the six-digit national ID # (format: *CTD000123*) has pushed from the Donor Management System to the organ allocation and transplant system correctly.
32. The CSC will run the Provincial Kidney Allocation.
33. The OOP HSP offer will be for a specific HSP Ontario recipient, the CSC will locate the recipient in the HSP section of the allocation.
34. If the HSP Ontario recipient does not appear in the “HSP Identified by CTR” section, the CSC will verify the following:
  - 34.1. The offering OPO has made the offer in CTR – If an offer has not been made in CTR, HSP recipients will not appear in the correct HSP heading on the allocation. In the event that the HSP recipient(s) are not appearing, the CSC will contact the offering OPO to ensure that the HSP offer(s) are made in CTR. Once the OPO has made the offer in CTR, the CSC will re-run the allocation to verify that the HSP recipients appear.
  - 34.2. The ECD box in the Donor Management System is set to “N/A” – HSP recipients may not have consented to ECD kidneys but will still be offered ECD kidneys as part of the HSP process because of the rare chance they will come back negative on VXM

#### ***Offering Process***

35. The CSC makes the kidney offer to the intended HSP recipient transplant program.

Note: If the VXM indicates a possible allele specific antibody to the donor, the CSC will contact the recipient HLA lab prior to offering to resolve the possible allele specific antibody, as outlined in *CPI-9-313, Organ Allocation*.

36. The CSC informs the OOP Donor OPO of the offer outcome.

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37. The CSC updates the organ allocation and transplant system and the Donor Management System to indicate accept or decline and reasons.

#### Recovery & Delivery Logistics for HSP – Ontario & OOP Donors

##### *Exporting an HSP Kidney to another Province*

38. Blood samples and spleen will be sent with the organ. However, if there is a significant duration of time between the time of organ acceptance to the time of recovery and a program is requesting blood for a stat cross match be sent ahead of time, the CSC may accommodate this request. All blood and spleen samples must be labelled with the donor CTD#.
39. For samples being sent with the organ, the CSC will verify with the accepting OOP OPO what samples are required and ensures the TGLN Surgical Recovery Coordinator (SRC) or designate is aware.
40. The OOP OPO is responsible for making flight arrangements for the organ and will notify the CSC with flight details.
41. If there are any specific legal or family requests to return the organ(s) to the body, the CSC will inform the receiving OPO coordinator.



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42. Prior to shipping the HSP kidney, the TGLN SRC or designate will ensure that the national ID # is included on:
- blood and organ specimen labels
  - paperwork accompanying the organ
43. Once the HSP kidney has been shipped to the OOP OPO, the CSC must indicate that the kidney has been sent for transplant by ticking off “HSP OOP Export” in the “Recovery Details” section of the Donor Profile in the organ allocation and transplant system.

#### ***Importing an HSP Kidney from another Province***

44. The CSC will notify the accepting Ontario transplant program’s regional HLA lab that a kidney is being imported from another province and provide them with an estimated time of arrival. The CSC will also confirm the required blood samples and/or spleen required for HLA testing upon arrival.
45. For HSP kidney imports, the CSC will send a kidney pump and kidney pump supplies to the OOP donor hospital prior to recovery, time permitting. Prior to making arrangements for sending the kidney pump, the CSC will ask the OOP OPO if their local recovery team is able to recover the kidney and place it on a kidney pump. If the OOP recovery team is unable to place the kidney on a pump, the CSC will notify the accepting Ontario transplant program that the kidney will not be pumped.
46. The CSC is responsible for making flight arrangements for the organ and will notify the OOP OPO with flight details.
47. The CSC will notify the Surgical Recovery Coordinator (SRC) or designate of the donor retrieval time and coordinate a plan for organ interception. See *Organ Delivery Process Instruction, CPI 9-405*.
48. If the intended HSP kidney recipient is unable to receive the transplant after it arrives at the recipient transplant centre, the CSC will re-allocate the kidney to another recipient at that same centre. If no other recipient is able to receive the kidney at that same centre, the CSC will allocate the kidney according to Ontario’s provincial kidney algorithm. If the kidney is re-allocated to a non-intended recipient, the CSC will update the organ allocation and transplant system to reflect this.

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#### Confirming Organ Outcome for HSP – Ontario & OOP Donors

49. If there are any surgical issues/concerns or anatomic abnormality noted by recovery staff during the recovery of an HSP kidney that is either being imported or exported, the CSC should ensure that the accepting transplant program, or OPO is aware.
50. In the event that an imported HSP kidney is deemed non-transplantable after recovery and delivery, the CSC informs the donor centre to determine if there are any specific legal or family requests to return the organ to the donor OPO/body. If there are no legal or family requests necessitating the kidney to be returned, the CSC will arrange disposal in accordance with the *Storage and Disposal of Organs Process Instruction, CPI-9-611*.
51. The CSC will document this communication in the clinical notes in the Donor Management System, and will update the organ outcome & disposition in both the Donor Management System and the organ allocation and transplant system.

#### HLA Issues Affecting Allocation of HSP Kidneys

52. If there are changes to the HLA typing of a donor after an allocation has been run, the CSC should notify programs that have accepted a kidney of the change, notify the CTR Customer Support Centre, and re-run the allocation to see if the changes affect the previous allocation report (i.e., Previous VXM negative recipients are now positive, or new VXM negative recipients appear before the already selected recipient on the list).
53. If the CSC receives an e-mail notification regarding “failure to upload” an HSP recipient or donor to CTR, the CSC follows the Business Continuity Plan for HSP. See *Business Continuity - Exchanging Recipient and Donor Data with Canadian Transplant Registry, OPI-9-103*.
54. If the CSC receives an error alert when attempting to run an allocation: “HLA typing incomplete”, the CSC will arrange for a conversation between the HLA lab that performed the donor typing and the potential recipient HLA lab. The CSC should call the same Ontario HLA contact that is consulted for allele specific decisions.

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#### Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Provincial Web Services Form	----	Provincial Resource Center	Donor Chart	16 years

#### References:

- *Disclosure of Donor and Recipient Personal Information to External Stakeholders during Offering, Acceptance and Recovery, CPI-9-1306*
- *Business Continuity - Exchanging Recipient and Donor Data with Canadian Transplant Registry, OPI-9-103*
- *Donor Assessment Process Instruction, CPI 9-208*
- *Organ Allocation, CPI-9-313*
- *Organ Delivery Process Instruction, CPI 9-405*