Clinical Process Instruction Manual

Coordination of Organ Placement – All Organs Process Instruction

Policy:

In accordance with provincial allocation algorithms, Ontario Health - Trillium Gift of Life Network (TGLN) facilitates the placement of all organs offered to Ontario recipients and donated from Ontario donors. Transplant programs and OPO's have two hours to accept or decline Highly Sensitized (HSP) kidney and High Status Heart (HSH) offers, and one hour to accept or decline all other organ offers. In some circumstances, further information is required to make an informed decision. In these cases, TGLN will make every effort to provide the additional information required in a timely manner. Organ offers made to Ontario from Canadian organ procurement organizations (OPO's) are accepted without exchange of funds (with the exception of transportation costs). Organ offers made to Ontario from U.S. OPO's that are accepted involve a Standard Acquisition Fee (SAF).

Families and/or healthcare professionals occasionally request to have suitability for donation assessed in advance of death determination by neurologic criteria and/or consent for donation. It is therefore occasionally necessary to discuss suitability of a potential donor on a hypothetical basis with the Transplant Support Physician (TSP) on-call, and/or transplant programs who in turn may decline the organ(s) based on either their assessment of risk versus benefit in relation to appropriate potential recipients, or such recipients' willingness to accept. The Clinical Services Coordinator (CSC) will explain to transplant programs that any discussions related to hypothetical referrals do not constitute an offer or guarantee a future offer to the transplant program.

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

Process:

1. In preparation for running organ allocation recommendations, the CSC will ensure the required donor information is entered into the database, including:
    - ABO (electronically signed)
    - ABO subtype, if applicable
    - consent parameters
    - height
    - weight
    - type of donor (Death determination by neurologic criteria [DNC] or Death determination by circulatory criteria [DCC])

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- serology
- HLA, if applicable
- extended criteria donor (ECD) identification, if applicable
- exceptional distribution (EXD) identification

2. The CSC will ensure a physical assessment and hemodilution calculation have been completed prior to allocation.

3. The CSC will submit the donor information to the organ allocation and transplant system to generate allocation recommendations for all consented organs.

4. When the allocation lists have been generated, two (2) CSCs must review the allocations as per *Allocation Verification Process Instruction, CPI-9-305*.

5. The CSC will upload the required donor information outlined in *Organ and Composite Tissue Specific Data Collection Process Instruction, CPI-9-215,* to the organ allocation and transplant system so that the Ontario transplant program(s) may determine medical suitability of offered organs.

6. The CSC will offer organs to Ontario transplant programs or Canadian OPO's in accordance with the Ontario organ allocation algorithms. The CSC will identify the patient(s) the organ is being offered to. At the time of organ offer, the CSC will ensure that the transplant program or Canadian OPO has access to a redacted copy of the donor chart and all relevant accompanying documents and reports.

   6.1. For Canadian OPOs participating in the interprovincial electronic sharing of donor data with TGLN, the CSC may send the donor chart and redacted donor documents directly to the OPOs donor management system, via a one-time donor data transfer. All offers of this nature must be accompanied by a phone call by the CSC to the OPO to advise of the offer. 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.

7. If there are no suitable recipients identified in Ontario or Canada, the CSC will explore offering eligible organs to the United Network for Organ Sharing (UNOS) in the United States (U.S.).

   7.1. For DCC heart offers to UNOS, in addition to all required donor information, the CSC will include the *DCC Heart Offers to U.S. Hospitals* and request that it be made available with the offers to the U.S. OPOs. See Sample 1.

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7.1.1. If the CSC receives questions from U.S. OPOs related to predicting the likelihood of donor death within an acceptable timeframe for transplant, the CSC will inform the Transplant Medical Lead - Donation or Donation Support Physician (DSP).

7.1.2. The DSP will speak with the Most Responsible Physician (MRP) at the donor hospital and summarize the current patient status. The CSC will provide this summary to the inquiring OPO(s).

7.2. Upon acceptance of a DCC heart by an OPO from the U.S., the CSC will notify the Specialist, Organ and Tissue Donation (SOTD) and Manager on Call (MOC) of the acceptance. The CSC will arrange a huddle to confirm details relates to DCC heart recovery by the U.S. OPO. See Appendix 1 *DCC heart to U.S. OPO Huddle Checklist*. The huddle will include the CSC, SOTD, MOC, Transplant Medical Lead - Donation and/or Transplant Medical Lead – Transplant, and Surgical Recovery Coordinator (SRC), if applicable.

7.3. The CSC will assist in coordinating an additional *DCC Heart Recovery Team Huddle* - see Sample 2. The huddle will be moderated by the Transplant Medical Lead - Donation and /or Transplant Medical Lead – Transplant and include the CSC, Specialist – Organ and Tissue Donation (SOTD), MOC, and Surgical Recovery Coordinator (SRC), if applicable, and a representative from each program that has accepted an organ from the donor.

8. If there has been a request to return any unused organs to the body, the CSC will advise at time of offer the need to return any unused organs that are not transplanted, the accepting program assumes the costs to return the organ(s) if outside of Ontario. If the Out of Province (OOP) OPO is unable or unwilling to accept responsibility for the necessary arrangements required to return unused organ(s), the organ(s) will not be offered. In this case, the CSC will inform the SOTD of the organ placement difficulties due to the special request. The SOTD will re-approach the family to discuss the special request to see if they might reconsider. The SOTD informs the CSC of the outcome of the family conversation. If the family rescinds their request to return un-transplanted organs to the body, the CSC re-offers the organ to the transplant program.

9. If at the time of offer a Transplant Program notes there may be an error in the listing criteria for the offered recipient, the CSC will document the details of the error in the donor chart. The CSC will request the Transplant Program make a timely correction of the error, pause the allocation process until the Transplant Program notifies the CSC the correction is made and request the Transplant Program contact the CSC once the correction is made. After corrections are made, the CSC will re-run the allocations to ensure organs are allocated as per Provincial algorithms. If corrections are not performed in a timely manner, the CSC will contact the Manager-on-Call (MOC) for guidance on how to proceed with the offering process.

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10. Upon acceptance of an organ for a specific patient, the CSC will verify with a 2nd CSC that the organ was allocated to the appropriate patient as outlined in *Allocation Verification Process Instruction, CPI-9-305*.

11. Upon acceptance of a DCC kidney, the CSC will determine if the donor is eligible for extended wait time for DCC kidney recovery, as outlined in Sample 3 Extended Wait Time for DCC Kidney Recovery. The donor is eligible if one or more of the following are true:

    - Donor is a standard criteria donor
    - A kidney has been allocated to a highly sensitized patient (HSP)

    11.1. If the donor is eligible for extended wait time for DCC kidney recovery, the CSC will confirm with the accepting kidney program(s) if they are willing to wait additional time, up to 3 hours, after WLSM for death to occur. The CSC will communicate this information to the kidney recovery team. The CSC will identify the need for a back-up candidate, if required.

    11.2. If the donor is eligible for extended wait time for DCC kidney recovery and the accepting kidney program(s) are willing to wait additional time, the CSC will confirm with the recovery team how long they will wait for death to occur to recover kidneys. The CSC will communicate this information to the SRC and SOTD. All recovery programs have agreed to wait 2.5 hours for death to occur on eligible donors and some programs may opt to wait up to 3 hours. In these cases that donors are eligible for extended wait time for DCC kidney recovery, if death has not occurred at 2 hours post WLSM, the recovery team will only wait additional time if the mean arterial pressure (MAP) at this time is equal to or less than 50mmHg. If the offer is declined:

12. If the Most Responsible Physician (MRP), Transplant Medical Lead - Donation, or Donation Support Physician (DSP) requests a review of a donor organ decline:

    12.1. The CSC will attempt to facilitate direct communications between the MRP/Transplant Medical Lead - Donation/DSP and the first transplant program physician who declined the donor organ for transplant.

    12.2. In the event the transplant program physician declines the request to discuss the organ decline decision, the CSC involves the TSP on call to assist the MRP/Transplant Medical Lead - Donation/DSP in trying to connect with the transplant physician.

    12.3. Failed attempts to connect the MRP, Transplant Medical Lead - Donation, or DSP with transplant program physicians about organ declines will be reported to the Manager on Call (MOC).

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13. The decision to conclude the offering process of a specific organ to all transplant programs and OOP OPO's shall be made by the CSC in consultation with TGLN TSP on-call and any relevant accepting transplant physician(s) or OPO's, when further offers would involve a delay which would be significant in relation to one of the following:
    - if the Intensive Care Unit (ICU) physician and/or SOTD indicate that recovery must proceed expeditiously due to donor instability and/or donor family needs;
    - the transplant physician(s) indicate that delaying donor recovery would compromise recipient outcomes;
    - delaying the recovery OR would have significant resource complications.
14. In circumstances where a conflict exists between competing priorities, the CSC will discuss the case with the involved transplant programs via a huddle with the SOTD, CSC, MOC, and the TSP on-call.

15. The CSC will obtain from/discuss with the accepting transplant program the following information:
    - identification of the donor recovery team/surgeon
    - need for stat or virtual cross-match. See *Histocompatibility Testing Process Instruction, CPI-9-216*
    - donor recovery/OR timing requests
    - transportation considerations. See *Transportation Coordination Process Instruction, CPI-9-404*,
    - follow-up communication regarding:
        - changes in timing affecting the recipient OR
        - expected communication during the donor recovery process
        - visualization of organ(s)
        - aortic cross-clamp
        - means of transportation for organs and timing involved
        - notification and timing of stat cross-match results
        - verification with the accepting physician or designate of who needs to be notified of delays or time changes.

16. If a transplant surgeon makes a request of a recovery surgeon, the CSC will attempt to put the transplant surgeon and recovery surgeon in direct communication with each other to discuss the request.

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17. When the recovery fellow assesses an organ as medically unsuitable in the donor OR, the SRC or designate who is present should request immediate discussion between the recovery fellow and the accepting transplant staff physician for a final assessment of medical suitability. If the organ is declined for transplant by the initial program, the SRC or designate will inform the CSC. Depending on the reason for decline and timing, the CSC may offer the organ out to other programs within Ontario. If unsure, the CSC may consult the TSP on-call regarding the need for further offers.

Offer from another Province or U.S. donor

18. Steps 1 - 17 are followed.

19. See *Non-Ontario Organ Donation Process Instruction, CPI-9-101* for out-of-province organ offer process.

Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Organ Allocation Report	——	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
- Donor Medical and Social History – Organ or Combined Organ & Tissue Process Instruction, CPI-9-207
- Donor Assessment Process Instruction, CPI-9-208
- Infectious Disease Testing – STAT Process Instruction, CPI-9-211
- Organ and Composite Tissue Specific Data Collection Process Instruction, CPI-9-215
- Histocompatibility Testing Process Instruction, CPI-9-216
- Exceptional Distribution Process Instruction, CPI-9-217

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- Allocation Verification Process Instruction, CPI-9-305
- Transportation Coordination Process Instruction, CPI-9-404

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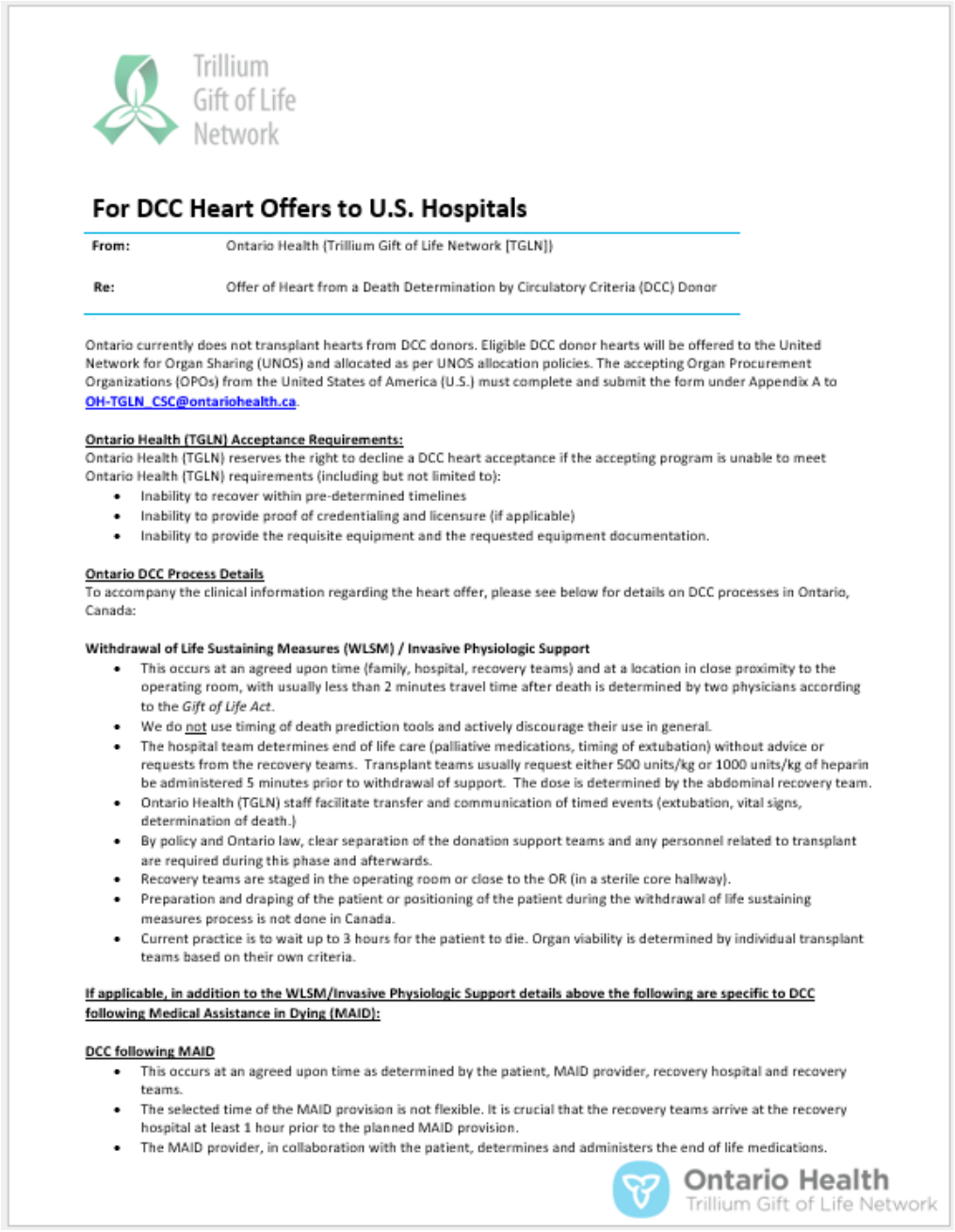
Sample 1: DCC Heart Offers to U.S. Hospitals



Trillium Gift of Life Network

For DCC Heart Offers to U.S. Hospitals

From: Ontario Health (Trillium Gift of Life Network [TGLN])

Re: Offer of Heart from a Death Determination by Circulatory Criteria (DCC) Donor

Ontario currently does not transplant hearts from DCC donors. Eligible DCC donor hearts will be offered to the United Network for Organ Sharing (UNOS) and allocated as per UNOS allocation policies. The accepting Organ Procurement Organizations (OPOs) from the United States of America (U.S.) must complete and submit the form under Appendix A to OH-TGLN_CSC@ontariohealth.ca.

Ontario Health (TGLN) Acceptance Requirements:
Ontario Health (TGLN) reserves the right to decline a DCC heart acceptance if the accepting program is unable to meet Ontario Health (TGLN) requirements (including but not limited to):

- Inability to recover within pre-determined timelines
- Inability to provide proof of credentialing and licensure (if applicable)
- Inability to provide the requisite equipment and the requested equipment documentation.

Ontario DCC Process Details
To accompany the clinical information regarding the heart offer, please see below for details on DCC processes in Ontario, Canada:

Withdrawal of Life Sustaining Measures (WLSM) / Invasive Physiologic Support

- This occurs at an agreed upon time (family, hospital, recovery teams) and at a location in close proximity to the operating room, with usually less than 2 minutes travel time after death is determined by two physicians according to the *Gift of Life Act*.
- We do not use timing of death prediction tools and actively discourage their use in general.
- The hospital team determines end of life care (palliative medications, timing of extubation) without advice or requests from the recovery teams. Transplant teams usually request either 500 units/kg or 1000 units/kg of heparin be administered 5 minutes prior to withdrawal of support. The dose is determined by the abdominal recovery team.
- Ontario Health (TGLN) staff facilitate transfer and communication of timed events (extubation, vital signs, determination of death.)
- By policy and Ontario law, clear separation of the donation support teams and any personnel related to transplant are required during this phase and afterwards.
- Recovery teams are staged in the operating room or close to the OR (in a sterile core hallway).
- Preparation and draping of the patient or positioning of the patient during the withdrawal of life sustaining measures process is not done in Canada.
- Current practice is to wait up to 3 hours for the patient to die. Organ viability is determined by individual transplant teams based on their own criteria.

If applicable, in addition to the WLSM/Invasive Physiologic Support details above the following are specific to DCC following Medical Assistance in Dying (MAID):

DCC following MAID

- This occurs at an agreed upon time as determined by the patient, MAID provider, recovery hospital and recovery teams.
- The selected time of the MAID provision is not flexible. It is crucial that the recovery teams arrive at the recovery hospital at least 1 hour prior to the planned MAID provision.
- The MAID provider, in collaboration with the patient, determines and administers the end of life medications.

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Appendix 1: DCC Heart to U.S. OPO Huddle Checklist

Ontario Health
Trillium Gift of Life Network

483 Bay Street South Tower, 4th Floor
Toronto, Ontario M5G2C9
Tel (24/7): 1.888.603.1399 Fax: 1.866.557.6100
Website: www.giftoflife.on.ca

DCC Heart to U.S. OPO Huddle Checklist

The CSC is responsible for arranging the team huddle and should include at a minimum: the CSC, SOTD, MOC, Transplant Medical Lead – Donation and/or Transplant Medical Lead – Transplant, and SRC, if applicable.

TGLN #: _____ Date: _____ Time: _____

CSC: _____ MOC: _____ SOTD: _____

Transplant Medical Lead – Donation or Transplant: _____ SRC: _____

	Completed	Requires Follow-Up
Overview by OTDC		
• Scheduled withdrawal time?	☐	☐
• Location of withdrawal?	☐	☐
• Plan for OTDC staffing?	☐	☐
• Other Hospital or family specific concerns	☐	☐
Overview by CSC		
CSC to review information provided by US OPO in Appendix A of the DCC Heart Offers to U.S. Hospitals package, including but not limited to, the following:		
• Is the heart being recovered by the transplant team or a third party?	☐	☐
• Number of team members with heart recovery team?	☐	☐
• Required credentials received for heart recovery team members?	☐	☐
• Have credentials been forwarded to Transplant Medical Lead to provide to donor hospital administrators?	☐	☐
• Is recovery support required from Dr. Alvarez?	☐	☐
• What heart perfusion machine is the team bringing?	☐	☐
• Have we received the required machine documents?	☐	☐
• How will the team get from the donor airport to the donor hospital?	☐	☐
• How will the team get from the donor hospital to the donor airport?	☐	☐
• If TGLN is required to assist with transportation, are there any specific transportation requirements TGLN needs to be aware of	☐	☐
• Confirmed that the heart recovery team is bring own required supplies/solutions?	☐	☐

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Sample 2: DCC Heart Recovery Team Huddle

DCC HEART POST-ACCEPTANCE HUDDLE:

As Ontario currently does not transplant hearts from DCC donors, eligible DCC donor hearts will be offered to the United Network for Organ Sharing (UNOS) and allocated as per UNOS allocation policies. Post-acceptance of the heart the US OPO must participate in a huddle before their arrival on-site with Ontario recovery teams and the TGLN team.

- This huddle will include the heart team, lung team, abdominal team, MOC, case manager, SOTD, SRC, CSC, and CMO Donation or DSP in their absence a delegate.
- CMO donation/DSP will assume the role of moderator.
- The CSC will arrange a huddle time and a Zoom set up between all parties involved.
- Please allow at least 30 minutes to discuss important details.

HUDDLE POINTS OF DISCUSSION:

1. Introduction of members on the call and their roles.
2. Confirmation of medical license, proof of insurance.
3. Quick overview of the DCC process in Ontario and death determination process and 5 minutes hands-off period – *refer to Appendix A.*
4. Heart Team Logistics: Travel time, set up time.
    - Airport details of arrival- proximity to the hospital.
    - Travel to and from the airport and the method.
    - Travel back to the airport and method.
5. Location of withdrawal and time from WLS location to the OR.
6. Heparin administration dose and process.
7. Heart wait times up to 3 hrs **or** until all organs are closed.
8. Share and confirm with other organ programs how long they plan to wait (lung, kidney, liver, pancreas).
9. Confirm: Heart fWIT definition = SBP < 50 to heart flush 30 minutes. If in first 5 minutes, the SBP recovers, the clock restarts. After that, no reset. - Heart team to discuss.
10. All other organs should speak about fWIT.
11. The heart team plans for blood collection from the donor – explain the process and confirm if the abdomen team still able to cut/canulate during these 3 minutes. The heart team must communicate to the liver team when it's appropriate for flushing.
    - The heart team needs to try to collect 1 to 1.5 L of donor blood (preferred over banked blood). Heart team to explain how this process will be performed and what type of equipment or support they need.
    - Usually, the blood collection can take up to 3 minutes from skin cut. The timer will be set for 3 minutes by the OTDC/designate in the OR. (This is usually well in advance of liver surgeons being ready to flush.)
    - Confirm that this will be possible. If the liver is ready to flush and it is approaching its time limit, it may only be able to give the heart 90s-2 minutes.
    - In the circumstance where blood collection is not possible from the IVC, x-matched banked (washed or not washed) blood can be made available.
12. Washed blood to be ordered ahead of time by SOTD.

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Sample 3: Extended Wait Time for DCC Kidney Recovery

Extended Wait Time for DCC Kidney Recovery

Purpose

Extending wait times in donation after death determination by circulatory criteria (DCC) kidney recovery has the potential to increase the number of transplantable kidneys in Ontario. DCC kidneys already make up around 30% of transplants.

Approximately 25% percent of potential DCC donors fail to donate organs. This has resource implications with unnecessary recipient admission, transportation costs, operating room resources and takes a toll on donor families and recovery teams.

Clinical studies having shown that increasing wait times up to 2 hours have not impacted clinical outcomes in recipients[1]. Recovery programs in Ontario have agreed to further increase wait times for Standard Criteria Donors

This practice aligns with practices in the BC and the UK and if applied, based on data from 2018-19, could result in approximately 14 additional kidney transplants from 7 donors. TGLN will continue to evaluate the implementation of this policy.

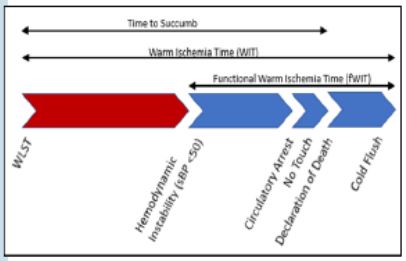
Extended Wait Time Inclusion Criteria

Kidney recovery teams will wait additional time for DCC kidney recovery if:

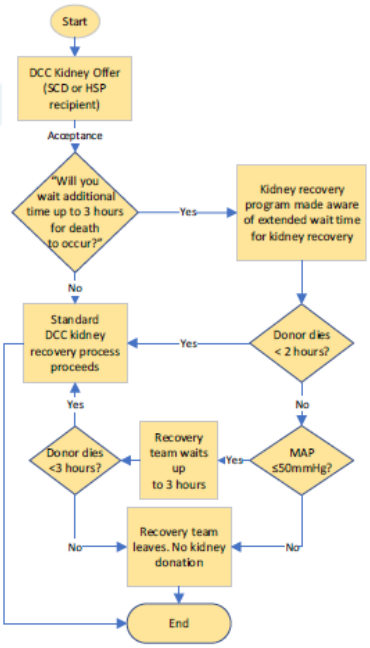
- SCD donor

or

- A kidney has been allocated to an HSP recipient



Process



[1] American Journal of Transplantation 2017; 17: 191–200

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