Clinical Process Instruction Manual

Perfusion & Packaging: Liver Process Instruction

Policy:

For cases where Trillium Gift of Life Network (TGLN) provides surgical recovery support, TGLN's Surgical Recovery Coordinator (SRC) or designate will facilitate perfusion and packaging of organs, using aseptic technique and in accordance otherwise with the *Health Canada Safety of Human Cells, Tissues and Organs for Transplantation Regulations*. For recovery procedures performed by the transplant programs, the transplant program's assigned designate undertakes surgical recovery activities including perfusion and packaging.

The SRC or designate refers to the *Clinical Services Coordinator to Surgical Recovery Coordinator Communication Process Instruction, CPI-9-406* prior to departing for recovery.

Process:

Prior to Departing TGLN

1. The SRC obtains the appropriate documentation required for recovery. Forms include:
    - *Reporting Form: Clinical Services Coordinator to Surgical Recovery Coordinator*
    - *Organ Donor Surgery Information*
    - *Liver Retrieval Operative Note* (See Exhibit 1) or *DCD Liver Retrieval Operative Note* (see Exhibit 2).
    - *Liver Transplant Operating Room Data or Liver / Kidney Transplant Operating Room Data* (with attached ABO and Serology).
      See Exhibit 3 for *Liver Transplant Operating Room Data.* See Exhibit 4 for *Liver/Kidney Transplant Operating Room Data.*
    - *Public Health Requisition* from Public Health, if required
    - *Laboratory Services Requisition: STAT Infectious Disease Testing of Organ Donors*, if required
    - Organ Labels
    - Specimen Labels
    - Surgical supply list, if needed

   For organ recoveries performed by transplant programs, the *Organ Donor Surgery Information* and the *Liver Transplant Operating Room Data* (if recipient was Ontario based) are sent back to TGLN's Provincial Resources Centre (PRC) for filing with the donor chart.

2. The SRC or designate prepares the abdominal organ surgical recovery kit. The SRC reviews the contents of the kit to ensure that all of the following required for the recovery are present:

- 2 sterile Y perfusion tubing
- 1 paediatric feeding tubes
- 1 – 60cc syringe
- 6 CardioMed organ bags
- 2 red top tubes (no additive)
- 2 purple top tubes
- 4 yellow top tubes (ACD)
- 2 pour spouts
- 3 specimen container (non-sterile)
- 10 specimen bags
- 2 sterile specimen containers
- 1 hammer (to break up slush if needed)
- 12 venous return cannulas (sizes 12,14,16,18,21 & 24)
- 10 microbiology requisitions
- 1 sterile abdominal retractor, if not provided at the recovery facility

3. The SRC confirms that all sealed items have not been tampered with, equipment is sterile and all supplies are within expiration dates. The SRC replaces supplies and/or equipment if there is any uncertainty regarding their integrity and places these supplies in a designated area in the surgical retrieval room.

4. The SRC obtains a large cooler from the TGLN surgical supply store room and places the following items within:
    - wet ice (fill 1/3 of the cooler)
    - 7 to 8L of Servator-B
    - 6 to 10 bags of slush (may break up slush at TGLN or recovery facility)

5. The SRC replaces depleted slush to maintain appropriate inventory of frozen slush, if required.

6. The SRC may require a small red styrofoam cooler to contain all unused supplies post-recovery that may require refrigeration.

7. The Clinical Services Coordinator (CSC) communicates to the SRC if the patient is a TGH Liver study candidate.

8. The SRC picks up the recovery team at predetermined time and location.

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Upon Arrival at Recovery Hospital

9. The SRC notifies the PRC of his/her arrival time.

10. The SRC introduces the recovery team to the Operating Room (OR) staff.

11. The SRC records the names of the OR staff, if time permits) and the donor hospital's civic address and contact information on the *Organ Donor Surgery Information.*

12. The SRC reviews the patient's chart with the recovery team, confirms ABO, serology results, declarations (if applicable), consent and Coroner involvement (if required). If required, the SRC discusses serology results with the Specialist - Organ and Tissue Donation (S-OTD) or CSC.

13. The SRC ensures all appropriate blood samples have been drawn and correctly labelled with TGLN identification number, donor date of birth, as well as date and time of collection. The samples are to be placed into specimen bags containing the appropriate requisitions.

14. The SRC asks the OR staff for 1 or 2 intravenous (IV) poles for use during perfusion, a table and 2 sterile basins for abdominal slush and liver packaging.

15. Prior to use, the frozen saline must be wrapped in a towel and hammered until broken up into a slush-like consistency.

16. The SRC opens and passes the following sterile supplies to the scrub nurse to remain on the OR supply table:
    - sterile abdominal retractor, if surgical staff request to use the TGLN retractor
    - paediatric feeding tube
    - 60cc syringe
    - portal cannula.

17. The SRC scrubs in as per aseptic protocol and prepares the back table with the assistance of the circulating nurse. See Figure 1. The following materials are required:
    - 2 sterile basins
    - 3 CardioMed organ bags
    - 2 sterile specimen container
    - 6 to 10 bags of crushed slush

    The SRC places one bag over the sterile basin. Depending on the size of the liver, the SRC will empty 1 to 2 bags of crushed slush into the basin. The SRC places the other two bags over the

existing bag of ice and leaves the ties next to the basin. The SRC empties the remaining bags of crushed slush into the empty sterile basin. This slush is to be used for abdominal cooling post aortic cross-clamp and should be located in close proximity to the OR table to ensure accessibility. The SRC removes the cap from the sterile specimen container and leaves it open on the packaging table.

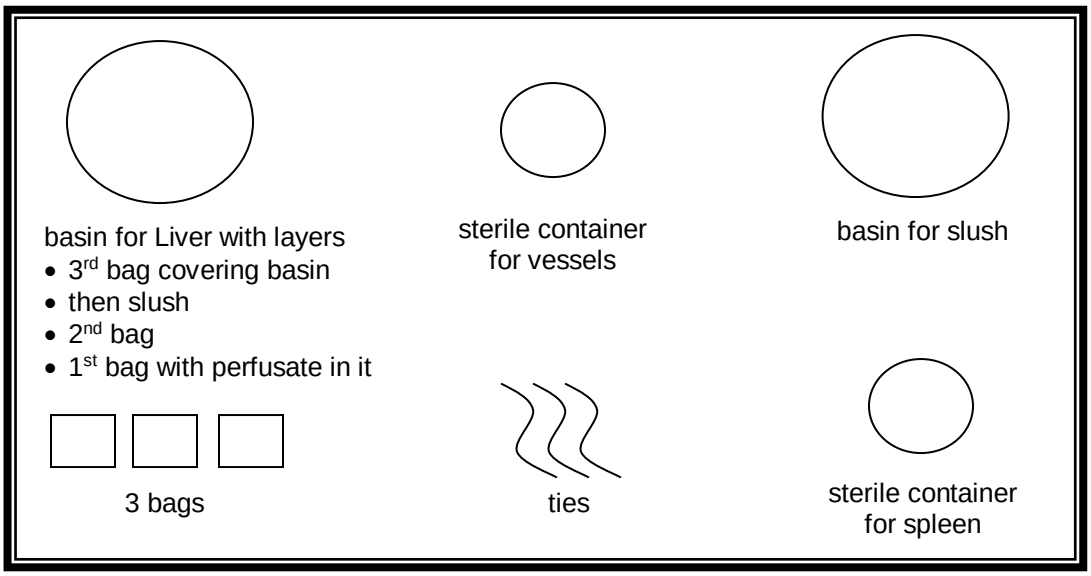

Figure 1: Sterile Back Table Set-up for Liver

18. The SRC breaks scrub and opens the sterile perfusion tubing to the scrub nurse. The SRC will then direct the scrub nurse to attach the 12F venous return cannula to the distal end of one of the sterile Y perfusion tubing sets (portal line), and will direct the scrub nurse to attach the 24F venous return cannula to the other perfusion line (aortic line). The recovery surgeon may specify alternate sizes for cannulas. Both sets of perfusion tubing are separately attached to the foot of the OR table by the scrub nurse.

19. The scrub nurse will then hand the SRC the other end of the perfusion tubing sets. The SRC attaches both the aortic and the portal perfusion lines to 2 separate IV poles. To avoid confusion, these lines may be labelled “aortic” and “portal.”

20. The SRC will discuss flushing requirements with recovery team, pressure infusers may be utilized at request of recovery team.

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Surgical Recovery

21. Upon commencement of surgical recovery, the SRC records the "skin cut time" on the *Organ Donor Surgery Information*, and notifies the CSC.

22. The SRC contacts the CSC when surgeons have assessed the donor liver, and gives and estimated time for aortic cross-clamp. Accordingly, the CSC contacts the transplant physician upon notification, if requested.

23. The SRC records the time of heparin administration and the number of units administered on the *Organ Donor Surgery Information*.

24. When cross-clamp is imminent, the SRC hangs 1 – 2L and 1 – 2L bag of Servator-B on the aortic line and 1 – 2L bag of Servator-B on the portal line. The perfusate amounts are subject to change as per request from surgical staff.

25. At cross-clamp, the SRC records the time and opens both the aortic and portal perfusion lines. The SRC will notify surgical staff as each litre of perfusate is used and stops perfusion upon request.

26. The SRC records name and volume of perfusion solutions and the name of storage solutions on the *Organ Donor Surgery Information.*

27. The SRC notifies the CSC of cross clamp time and estimated time of departure.

28. Using a pour spout, the SRC decants 1L to 2L of Servator-B into the sterile basin on the packaging table. Also, approximately 40cc of Servator-B is decanted into the small specimen container for vessel transport.

29. The recovery surgeon places the liver in the top of bag with solution and the top is tied off and secured with umbilical ties. The 2nd cardiomed bag is tied off and secured with an umbilical tie. The above step is repeated with the 3rd bag.

30. The recovered vessels are packaged and labelled in accordance with *Coordination and Recovery of Adjunct Vessels for use in Solid Organ Transplants, CPI-9-1007* with the exception that if they are to be used in the liver transplant, then they can be placed in the same cooler as the liver.

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31. Recovered vessels are packaged and labelled in accordance with *Coordination and Recovery of Adjunct Vessels for use in Solid Organ Transplants, CPI-9-1007* with no exceptions.

32. The SRC labels the packaged liver as per *Organ and Composite Tissue Labelling Process Instruction, CPI-9-417.* The organ bag is then placed into a large cooler and sufficiently covered with ice.

Prior to Departing Recovery Hospital

33. A copy of the *Liver Retrieval Operative Note* is completed, signed by the appropriate surgical staff and left in the hospital donor chart.

34. Surgical staff may document any abnormalities or other comments on the *Organ Donor Surgery Information*, if necessary.

35. The SRC notifies the CSC and provides the aforementioned information, as well as their time of departure.

36. If unaccompanied by a member of the recovery team to the recipient OR, the SRC ensures the cooler is secured with a one-time use fastener. If accompanied by a recovery team member, it is not mandatory to secure a cooler.

Post Recovery

37. The SRC ensures all lot numbers and expiry dates of all solutions and supplies used are recorded on the surgical supply list.

38. The SRC ensures that donor blood, sputum, spleen, etc. samples are dropped off at the appropriate locations as per *Infectious Disease Testing – STAT Process Instruction, CPI-9-211*, *Infectious Disease Testing – Non-STAT Process Instruction, CPI-9-213* and *Microbiology Testing Process Instruction, CPI-9-214.*

39. The SRC ensures that the TGLN retractor set is dropped off at TGH to be sterilized as per *Sterilization of Equipment – Organ Process Instruction, CPI-9-708, if used.*

40. The SRC repacks the surgical recovery kit upon completion of organ recovery.

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Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Surgical Supply List	CSF-9-58	PRC	PRC	16 years
Organ Donor Surgery Information	CSF-9-57	PRC	PRC	16 years
Liver Transplant Operating Room Data	CSF-9-40	PRC	PRC	16 years
Liver/Kidney Transplant Operating Room Data	CSF-9-181	PRC	PRC	16 years
Liver Retrieval Operative Note	CSF-9-41	PRC	PRC	16 years
DCD Liver Retrieval Operative Note	CSF-9-39	PRC	PRC	16 years

References:

- Infectious Disease Testing – STAT Process Instruction, CPI-9-211
- Infectious Disease Testing – Non-STAT Process Instruction, CPI-9-213
- Microbiology Testing Process Instruction, CPI-9-214
- Clinical Services Coordinator to Surgical Recovery Coordinator Communication Process Instruction, CPI-9-406
- Organ and Composite Tissue Labelling Process Instruction, CPI-9-417

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- Sterilization of Equipment – Organ Process Instruction, CPI-9-708
- Coordination and Recovery of Adjunct Vessels for use in Solid Organ Transplants, CPI-9-1007
- Safety of Human Cells, Tissues and Organs for Transplantation Regulations, Health Canada, June 2007
- Health Canada Guidance Document for Cell, Tissue and Organ Establishments

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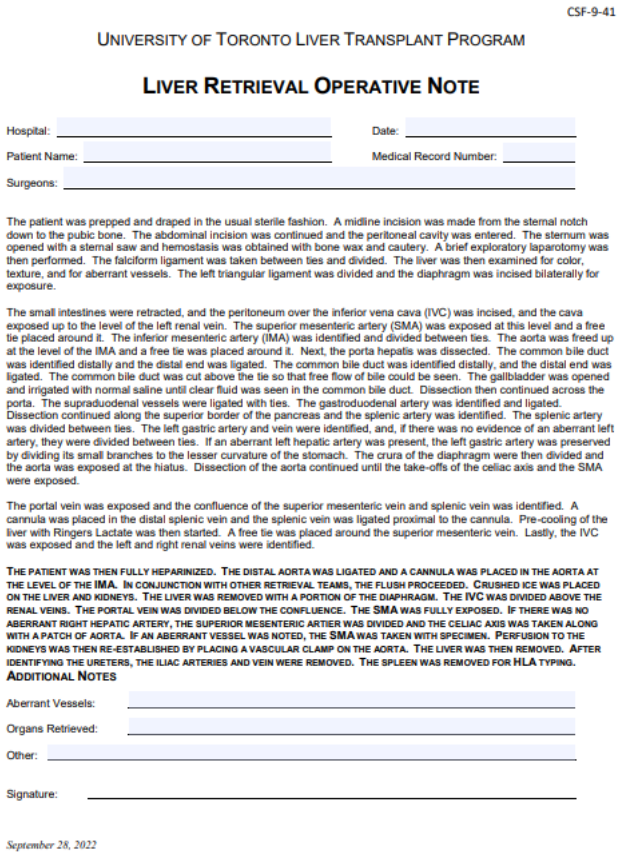
Exhibit 1: Liver Retrieval Operative Note



CSF-9-41

UNIVERSITY OF TORONTO LIVER TRANSPLANT PROGRAM

LIVER RETRIEVAL OPERATIVE NOTE

Hospital: _____ Date: _____

Patient Name: _____ Medical Record Number: _____

Surgeons: _____

The patient was prepped and draped in the usual sterile fashion. A midline incision was made from the sternal notch down to the pubic bone. The abdominal incision was continued and the peritoneal cavity was entered. The sternum was opened with a sternal saw and hemostasis was obtained with bone wax and cautery. A brief exploratory laparotomy was then performed. The falciform ligament was taken between ties and divided. The liver was then examined for color, texture, and for aberrant vessels. The left triangular ligament was divided and the diaphragm was incised bilaterally for exposure.

The small intestines were retracted, and the peritoneum over the inferior vena cava (IVC) was incised, and the cava exposed up to the level of the left renal vein. The superior mesenteric artery (SMA) was exposed at this level and a free tie placed around it. The inferior mesenteric artery (IMA) was identified and divided between ties. The aorta was freed up at the level of the IMA and a free tie was placed around it. Next, the porta hepatis was dissected. The common bile duct was identified distally and the distal end was ligated. The common bile duct was identified distally, and the distal end was ligated. The common bile duct was cut above the tie so that free flow of bile could be seen. The gallbladder was opened and irrigated with normal saline until clear fluid was seen in the common bile duct. Dissection then continued across the porta. The supraduodenal vessels were ligated with ties. The gastroduodenal artery was identified and ligated. Dissection continued along the superior border of the pancreas and the splenic artery was identified. The splenic artery was divided between ties. The left gastric artery and vein were identified, and, if there was no evidence of an aberrant left artery, they were divided between ties. If an aberrant left hepatic artery was present, the left gastric artery was preserved by dividing its small branches to the lesser curvature of the stomach. The crura of the diaphragm were then divided and the aorta was exposed at the hiatus. Dissection of the aorta continued until the take-offs of the celiac axis and the SMA were exposed.

The portal vein was exposed and the confluence of the superior mesenteric vein and splenic vein was identified. A cannula was placed in the distal splenic vein and the splenic vein was ligated proximal to the cannula. Pre-cooling of the liver with Ringers Lactate was then started. A free tie was placed around the superior mesenteric vein. Lastly, the IVC was exposed and the left and right renal veins were identified.

THE PATIENT WAS THEN FULLY HEPARINIZED. THE DISTAL AORTA WAS LIGATED AND A CANNULA WAS PLACED IN THE AORTA AT THE LEVEL OF THE IMA. IN CONJUNCTION WITH OTHER RETRIEVAL TEAMS, THE FLUSH PROCEEDED. CRUSHED ICE WAS PLACED ON THE LIVER AND KIDNEYS. THE LIVER WAS REMOVED WITH A PORTION OF THE DIAPHRAGM. THE IVC WAS DIVIDED ABOVE THE RENAL VEINS. THE PORTAL VEIN WAS DIVIDED BELOW THE CONFLUENCE. THE SMA WAS FULLY EXPOSED. IF THERE WAS NO ABERRANT RIGHT HEPATIC ARTERY, THE SUPERIOR MESENTERIC ARTIER WAS DIVIDED AND THE CELIAC AXIS WAS TAKEN ALONG WITH A PATCH OF AORTA. IF AN ABERRANT VESSEL WAS NOTED, THE SMA WAS TAKEN WITH SPECIMEN. PERFUSION TO THE KIDNEYS WAS THEN RE-ESTABLISHED BY PLACING A VASCULAR CLAMP ON THE AORTA. THE LIVER WAS THEN REMOVED. AFTER IDENTIFYING THE URETERS, THE ILIAC ARTERIES AND VEIN WERE REMOVED. THE SPLEEN WAS REMOVED FOR HLA TYPING.

ADDITIONAL NOTES

Aberrant Vessels: _____

Organs Retrieved: _____

Other: _____

Signature: _____

September 28, 2022

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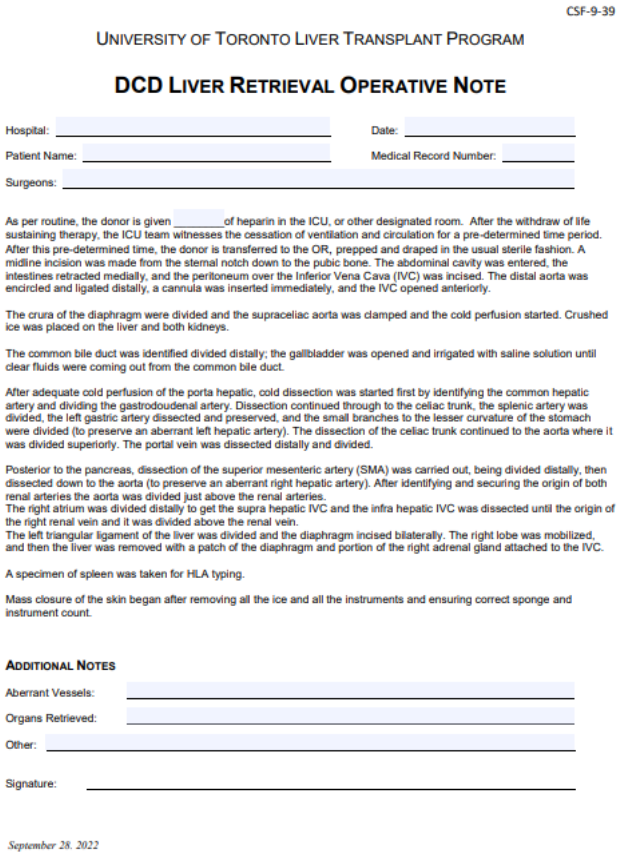
Exhibit 2: DCD Liver Retrieval Operative Note



CSF-9-39

UNIVERSITY OF TORONTO LIVER TRANSPLANT PROGRAM

DCD LIVER RETRIEVAL OPERATIVE NOTE

Hospital: _____ Date: _____

Patient Name: _____ Medical Record Number: _____

Surgeons: _____

As per routine, the donor is given _____of heparin in the ICU, or other designated room. After the withdraw of life sustaining therapy, the ICU team witnesses the cessation of ventilation and circulation for a pre-determined time period. After this pre-determined time, the donor is transferred to the OR, prepped and draped in the usual sterile fashion. A midline incision was made from the sternal notch down to the pubic bone. The abdominal cavity was entered, the intestines retracted medially, and the peritoneum over the Inferior Vena Cava (IVC) was incised. The distal aorta was encircled and ligated distally, a cannula was inserted immediately, and the IVC opened anteriorly.

The crura of the diaphragm were divided and the supraceliac aorta was clamped and the cold perfusion started. Crushed ice was placed on the liver and both kidneys.

The common bile duct was identified divided distally; the gallbladder was opened and irrigated with saline solution until clear fluids were coming out from the common bile duct.

After adequate cold perfusion of the porta hepatic, cold dissection was started first by identifying the common hepatic artery and dividing the gastroduodenal artery. Dissection continued through to the celiac trunk, the splenic artery was divided, the left gastric artery dissected and preserved, and the small branches to the lesser curvature of the stomach were divided (to preserve an aberrant left hepatic artery). The dissection of the celiac trunk continued to the aorta where it was divided superiorly. The portal vein was dissected distally and divided.

Posterior to the pancreas, dissection of the superior mesenteric artery (SMA) was carried out, being divided distally, then dissected down to the aorta (to preserve an aberrant right hepatic artery). After identifying and securing the origin of both renal arteries the aorta was divided just above the renal arteries.
The right atrium was divided distally to get the supra hepatic IVC and the infra hepatic IVC was dissected until the origin of the right renal vein and it was divided above the renal vein.
The left triangular ligament of the liver was divided and the diaphragm incised bilaterally. The right lobe was mobilized, and then the liver was removed with a patch of the diaphragm and portion of the right adrenal gland attached to the IVC.

A specimen of spleen was taken for HLA typing.

Mass closure of the skin began after removing all the ice and all the instruments and ensuring correct sponge and instrument count.

ADDITIONAL NOTES

Aberrant Vessels: _____

Organs Retrieved: _____

Other: _____

Signature: _____

September 28, 2022

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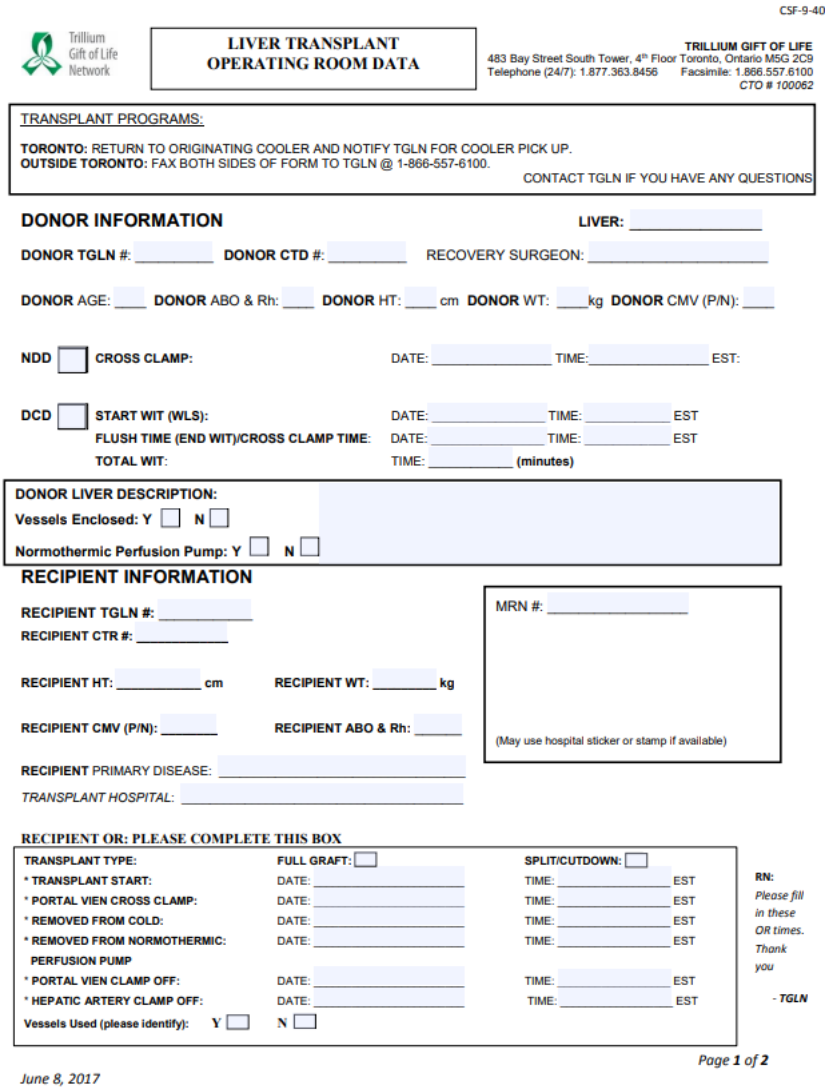
Exhibit 3: Liver Transplant Operating Room Data – Page 1



CSF-9-40

Trillium Gift of Life Network

LIVER TRANSPLANT OPERATING ROOM DATA

TRILLIUM GIFT OF LIFE
483 Bay Street South Tower, 4th Floor Toronto, Ontario M5G 2C9
Telephone (24/7): 1.877.363.8456 Facsimile: 1.866.557.6100
CTO # 100062

TRANSPLANT PROGRAMS:

TORONTO: RETURN TO ORIGINATING COOLER AND NOTIFY TGLN FOR COOLER PICK UP.
OUTSIDE TORONTO: FAX BOTH SIDES OF FORM TO TGLN @ 1-866-557-6100.
CONTACT TGLN IF YOU HAVE ANY QUESTIONS

DONOR INFORMATION **LIVER:** _____

DONOR TGLN #: _____ **DONOR CTD #:** _____ RECOVERY SURGEON: _____

DONOR AGE: ____ **DONOR** ABO & Rh: ____ **DONOR** HT: ____ cm **DONOR** WT: ____kg **DONOR** CMV (P/N): ____

NDD ☐ **CROSS CLAMP:** DATE: _____ TIME: _____ EST:

DCD ☐ **START WIT (WLS):** DATE: _____ TIME: _____ EST
FLUSH TIME (END WIT)/CROSS CLAMP TIME: DATE: _____ TIME: _____ EST
TOTAL WIT: TIME: _____ **(minutes)**

DONOR LIVER DESCRIPTION:
Vessels Enclosed: Y ☐ **N** ☐
Normothermic Perfusion Pump: Y ☐ **N** ☐

RECIPIENT INFORMATION

RECIPIENT TGLN #: _____
RECIPIENT CTR #: _____

MRN #: _____
(May use hospital sticker or stamp if available)

RECIPIENT HT: _____ **cm** **RECIPIENT WT:** _____ **kg**

RECIPIENT CMV (P/N): _____ **RECIPIENT ABO & Rh:** _____

RECIPIENT PRIMARY DISEASE: _____
TRANSPLANT HOSPITAL: _____

RECIPIENT OR: PLEASE COMPLETE THIS BOX

TRANSPLANT TYPE:	**FULL GRAFT:** ☐		**SPLIT/CUTDOWN:** ☐
* **TRANSPLANT START:**	DATE: _____	TIME: _____	EST
* **PORTAL VIEN CROSS CLAMP:**	DATE: _____	TIME: _____	EST
* **REMOVED FROM COLD:**	DATE: _____	TIME: _____	EST
* **REMOVED FROM NORMOTHERMIC PERFUSION PUMP**	DATE: _____	TIME: _____	EST
* **PORTAL VIEN CLAMP OFF:**	DATE: _____	TIME: _____	EST
* **HEPATIC ARTERY CLAMP OFF:**	DATE: _____	TIME: _____	EST
Vessels Used (please identify):	**Y** ☐	**N** ☐	

RN:
Please fill in these OR times. Thank you
- TGLN

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June 8, 2017

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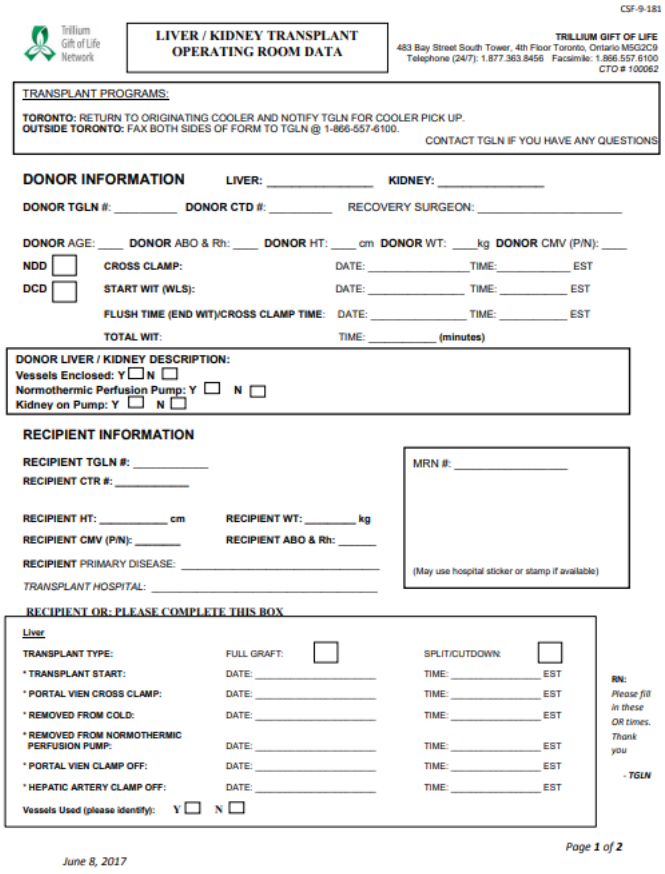
Exhibit 4: Liver / Kidney Transplant Operating Room Data
Page 1



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Trillium Gift of Life Network

LIVER / KIDNEY TRANSPLANT OPERATING ROOM DATA

TRILLIUM GIFT OF LIFE
483 Bay Street South Tower, 4th Floor Toronto, Ontario M5G2C9
Telephone (24/7): 1.877.363.8456 Facsimile: 1.866.557.6100
CTO # 100062

TRANSPLANT PROGRAMS:

TORONTO: RETURN TO ORIGINATING COOLER AND NOTIFY TGLN FOR COOLER PICK UP.
OUTSIDE TORONTO: FAX BOTH SIDES OF FORM TO TGLN @ 1-866-557-6100.
CONTACT TGLN IF YOU HAVE ANY QUESTIONS

DONOR INFORMATION **LIVER:** _____ **KIDNEY:** _____

DONOR TGLN #: _____ **DONOR CTD #:** _____ RECOVERY SURGEON: _____

DONOR AGE: ___ **DONOR** ABO & Rh: ___ **DONOR** HT: ___ cm **DONOR** WT: ___kg **DONOR** CMV (P/N): ___

NDD ☐ **CROSS CLAMP:** DATE: _____ TIME: _____ EST

DCD ☐ **START WIT (WLS):** DATE: _____ TIME: _____ EST

FLUSH TIME (END WIT)/CROSS CLAMP TIME: DATE: _____ TIME: _____ EST

TOTAL WIT: TIME: _____ **(minutes)**

DONOR LIVER / KIDNEY DESCRIPTION:
Vessels Enclosed: Y ☐ N ☐
Normothermic Perfusion Pump: Y ☐ N ☐
Kidney on Pump: Y ☐ N ☐

RECIPIENT INFORMATION

RECIPIENT TGLN #: _____
RECIPIENT CTR #: _____

MRN #: _____
(May use hospital sticker or stamp if available)

RECIPIENT HT: _____ **cm** **RECIPIENT WT:** _____ **kg**

RECIPIENT CMV (P/N): _____ **RECIPIENT ABO & Rh:** _____

RECIPIENT PRIMARY DISEASE: _____

TRANSPLANT HOSPITAL: _____

RECIPIENT OR: PLEASE COMPLETE THIS BOX

Liver

TRANSPLANT TYPE:	FULL GRAFT: ☐		SPLIT/CUTDOWN: ☐	
*** TRANSPLANT START:**	DATE: _____	TIME: _____	EST	
*** PORTAL VIEN CROSS CLAMP:**	DATE: _____	TIME: _____	EST	
*** REMOVED FROM COLD:**	DATE: _____	TIME: _____	EST	
*** REMOVED FROM NORMOTHERMIC PERFUSION PUMP:**	DATE: _____	TIME: _____	EST	
*** PORTAL VIEN CLAMP OFF:**	DATE: _____	TIME: _____	EST	
*** HEPATIC ARTERY CLAMP OFF:**	DATE: _____	TIME: _____	EST	

Vessels Used (please identify): Y ☐ N ☐

RN:
Please fill in these OR times. Thank you
- TGLN

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