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APPROVED BY: Organ Authority

Clinical Process Instruction Manual

Perfusion & Packaging:

Whole Pancreas, Kidney-Pancreas and/or Pancreas for Islets 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 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/Pancreas Retrieval Operative Note (see Exhibit 1) or DCD Liver/Kidney/Pancreas Retrieval Operative Note (see Exhibit 2).
 - Kidney/Pancreas Transplant Operating Room Data, Pancreas Transplant Operating Room Data, or Pancreas For Islets Transplant Operating Room Data (with attached ABO and Serology). See Exhibit 3 for the Kidney/Pancreas Transplant Operating Room Data. See Exhibit 4 for the Pancreas Transplant Operating Room Data. See Exhibit 5 for the Pancreas For Islets Transplant Operating Room Data.
 - HLA Lab Requisition Form
 - Public Health Ontario: General Test Requisition (if required)
 - Laboratory Services Requisition: STAT/NON-STAT Infectious Disease Testing of Organ Donors (if required)
 - Surgical supply list (if needed)
 - Organ Labels
 - Specimen Labels

For organ recoveries performed by transplant programs, the *Organ Donor Surgery Information* and the *Kidney/Pancreas Transplant Operating Room Data* or *Pancreas 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.

Note: Separate cooler sheets are required when <u>TGH</u> accepts an organ combination and/or cluster.



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- 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 supplies are present:
 - 3 sterile Y perfusion tubing
 - 8 CardioMed organ bags
 - 2 red top tubes
 - 2 portal tubing
 - 2 purple top tubes
 - 4 yellow top tubes (ACD)
 - 4 pour spouts
 - 2 Gastrointestinal Anastomosis (GIA) staplers
 - 9 GIA stapler refills
 - 3 specimen containers (non-sterile)
 - 3 specimen containers (sterile)
 - 2 large organ jars
 - 10 specimen bags
 - 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)
 - 1 sterile sternal saw (if not provided at the recovery facility)
- 3. The SRC confirms that all sealed items have not been compromised, equipment is sterile and all supplies are within expiration dates. The SRC replaces supplies and/or equipment if there is any uncertainty with respect to its integrity and places these supplies in a designated area in the surgical retrieval room.
- 4. The SRC obtains one large cooler from the TGLN surgical supply store room and places the following items within:
 - wet ice (fill 1/3 of the cooler)
 - 8 10L 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 also obtains a small red cooler to transport the pancreas, lines it with a yellow bag and fills ½ full with wet ice.
- 7. The SRC picks up the recovery team at predetermined time and location.



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Upon Arrival at Recovery Hospital

- 8. The SRC notifies the PRC of his/her arrival time.
- 9. The SRC records the names of the Operating Room (OR) staff (if time permits) and the civic addresses of the donor hospital and contact information on the *Organ Donor Surgery Information*.
- 10. The SRC introduces the recovery team to the OR staff.
- 11. The SRC reviews the patient's chart with the recovery team and confirms:
 - ABO,
 - serology results,
 - declarations,
 - consent and coroner involvement (if required)
- 12. 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. The SRC should consult the PRC when the pancreas is allocated outside the Greater Toronto Area (GTA), to ensure that all necessary blood work is performed.
- 13. 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 ice and organ rinsing.
- 14. The SRC opens the following sterile supplies to the scrub nurse to remain on the OR supply table:
 - 1 sterile abdominal retractor (if surgical staff request the use of the TGLN retractor)
 - 1 venous return cannula (size to be determined by surgical staff if needed)
 - 1 GIA stapler
 - 3 GIA stapler refills
 - 1 portal tubing (cannula)
 - 2 sterile Y perfusion sets
- 15. Prior to use, the frozen saline must be wrapped in a towel and hammered until broken up into slush-like consistency.
- 16. 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 for the packaging of the pancreas:



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- 3 sterile basins
- 2 CardioMed organ bags
- 1 large organ jar
- 6 to 10 bags of crushed slush (or 3 CardioMed organ bags due to size)
- 16.1. The SRC removes the cover from the large organ jar and places it near the edge of the packaging table. Two bags of crushed slush are opened into one of the sterile basins and placed next to the organ jar. The SRC empties the remaining bags of crushed slush into an 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.

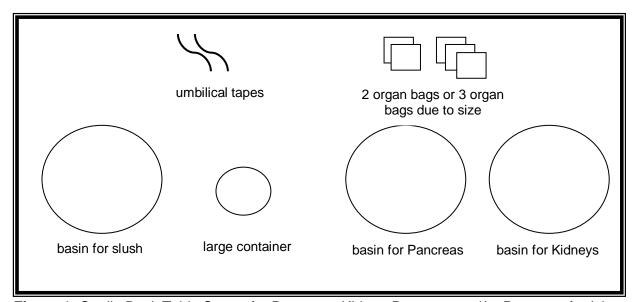


Figure 1: Sterile Back Table Set-up for Pancreas, Kidney-Pancreas and/or Pancreas for Islets

- 17. The SRC will direct the scrub nurse to secure the portal cannula to the distal end of one of the Y tubing sets and the aortic cannula to the distal end of the other Y tubing sets. Then both perfusion sets will be secured to the foot of the OR table by the scrub nurse.
- 18. The SRC is handed the proximal ends of the perfusion Y tubing and attaches them onto the IV pole provided. To avoid confusion, these lines may be labelled "aortic" and "portal". For whole pancreas for transplant only aortic line will be used.
- 19. With the aid of the scrub nurse, the SRC uses the perfusion solution to flush both the aortic and portal perfusion lines to ensure that all air is removed.



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Surgical Recovery

- 20. Upon commencement of surgical recovery, the SRC records the "skin cut time" on the *Organ Donor Surgery Information*, and notifies the CSC.
- 21. The SRC will contact the CSC when surgeons have assessed the suitability of the donor pancreas and/or kidney. Accordingly, the CSC contacts the transplant physician upon notification.
- 22. The SRC records the time of heparin administration and the number of units administered on the *Organ Donor Surgery Information*.
- 23. When cross-clamp is imminent, the SRC hangs between 2L to 3L of Servator-B on the aortic perfusion line, and 2L of Servator-B on the portal line. The perfusate amounts, as well as solution, are subject to change as per request from surgical staff.
- 24. At cross-clamp, the SRC records the time and commences aortic/portal perfusion. The SRC will notify surgical staff as each litre of perfusate is used and stops perfusion upon request.
- 25. SRC records name and volume of perfusion solutions, and name of storage solutions on the Organ Donor Surgery Information.
- 26. The SRC notifies the CSC of cross-clamp time and estimated time of departure.
- 27. Using a pour spout the SRC decants approximately 750mL of Servator-B into the basin on the packaging table. The pancreas will be packaged into 3 separate barriers, usually consisting of 3 CardioMed bags. The Recovery Surgeon places the recovered liver in the top of bag with solution and top is tied off and secured with umbilical ties. The second CardioMed bag is tied off and secured with umbilical tie. The above step is repeated with the 3rd bag.
- 28. The SRC obtains a splenic/lymph node sample from the surgical staff and places it in a small sterile specimen container filled with perfusate solution or normal saline. A second splenic sample may be required when the pancreas is being shipped to another Organ Procurement Organization (OPO). The container is appropriately labelled with:
 - the contents,
 - TGLN identification number,
 - · donor date of birth, and
 - · date and time of collection

The container is then placed into a specimen bag with the HLA Lab Requisition Form.



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- 29. If surgical staff require vessels, the SRC will obtain them in accordance with *Coordination and Recovery of Adjunct Vessels for use in Solid Organ Transplants, CPI-9-1007* and may be placed in the same cooler as the organ.
- 30. The SRC labels the packaged pancreas as per *Organ and Composite Tissue Labelling Process Instruction, CPI-9-417.* The organ bag is then placed into a small red cooler and sufficiently covered with ice. If the pancreas has been allocated to an out-of-province OPO, the SRC ensures that the cooler contains the following items:
 - splenic sample
 - appropriate number of blood samples
 - · donor serology and ABO results
 - Transport of Live Vital Organs

Prior to Departing Recovery Hospital

- 31. A copy of the *Liver/Pancreas Retrieval Operative Note* is completed and signed by the appropriate surgical staff and left in the hospital donor chart.
- 32. Surgical staff may document any abnormalities or other comments, on the *Organ Donor Surgery Information*, if necessary.
- 33. The SRC ensures all the labels are completed appropriately.
- 34. The SRC ensures all lot numbers and expiry dates of all supplies and solutions used are recorded on the surgical supply list.
- 35. 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.
- 36. The SRC notifies the CSC and provides a report of any abnormalities or comments previously reported, as well as their time of departure.

Post Recovery

- 37. Upon arrival at the recipient hospital OR or airport facility, the SRC delivers the organ(s) to the appropriate staff. The SRC and OR staff must review all documentation and organ label(s).
- 38. The SRC ensures that donor blood, spleen, etc. samples are dropped off at the appropriate locations as per *Infectious Disease Testing STAT Process Instruction, CPI-9-211* and *Infectious Disease Testing Non-STAT Process Instruction, CPI-9-213.*



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- 39. The SRC ensures that the TGLN retractor set and saw are dropped off at TGH to be sterilized as per *Sterilization of Equipment Organ Process Instruction, CPI-9-708*, if used.
- 40. The SRC ensures all lot numbers and expiry dates of all solutions and supplies used are recorded on the surgical supply list.
- 41. The SRC repacks the abdominal organ surgical recovery kit upon completion of organ recovery.

Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Organ Donor Surgery Information	CSF-9-57	PRC	PRC	16 years
Surgical Supply List	CSF-9-58	PRC	PRC	16 years
HLA Lab Requisition Form	CSF-9-23	PRC	PRC	16 years
Liver/Pancreas Retrieval Operative Note	CSF-9-50	PRC	PRC	16 years
Pancreas Transplant Operating Room Data	CSF-9-49	PRC	PRC	16 years
Kidney/Pancreas Transplant Operating Room Data	CSF-9-48	PRC	PRC	16 years
Pancreas for Islets Transplant Operating Room Data	CSF-9-113	PRC	PRC	16 years



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References:

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



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Exhibit 1: Liver/Pancreas Retrieval Operative Note

25 January 2023

DNIVERSITY OF TORONI	TO LIVER / PANCREAS TRANSPLANT PROGRAM			
LIVER / PANCREAS RETRIEVAL OPERATIVE NOTE				
Hospital:	Date:			
Patient Name:	Medical Record Number:			
Surgeons:				
down to the pubic bone. The abdominal inci opened with a sternal saw. A brief explorato The liver was then examined for colour, textu	usual sterile fashion. A midline incision was made from the sternal notch sion was continued and the peritoneal cavity was entered. The sternum was ny was then performed. The falciform ligament was divided between ties. ure, and for aberrant vessels. The left triangular ligament was divided and the re. 200 grams of IV Mannitol and 120cc of Betadine were injected into the t.			
vena cava (IVC) exposed up to the level of it level. The inferior mesenteric artery was ide around it. Next, the portal hepatic was disse could be seen. The gallibadder was opened duct. Dissection then continued across the p artery was identified and ligated. Dissection was identified. The left gastric artery and ve	ding colon, duodenum, and head of pancreas were mobilized and the inferior he left renal vein. The small mesenteric artery (SMA) was exposed at this miffied and divided, the aorta was freed up distal to this, and free ties placed coted. The common bile duct was cut above the tie so that free flow of bile land irrigated with normal saline until clear fluid was seen in the common bile out. The supraduodenal vessels were ligated with ties. The gastroduoden continued along the superior border of the pancreas and the splenic artery in were identified and, if there was no evidence of an aberrant left hepatic aberrant left hepatic artery was present, the left gastric artery was preserver unvature of the stomach.			
pancreas and the small mesenteric vein (SM and divided between ties. The pancreas wa the pancreas was dissected off the retroperit The superior edge of the pancreas was disse	entire gastrocolic ligament. The transverse mesocolon was dissected off the IV) identified inferior to the pancreas. Short gastric vessels were identified is then assessed and deemed suitable for procurement. The inferior border toneum and the spleen mobilized by dividing its ligamentous attachments educed and the distal pancreas mobilized to the splenic artery origin. The notics. The ligament of the Treitz was divided and the fourth part of the			
stay sutures of Prolene were placed at a poin heparinized. The distal aonta was ligated an solution proceeded. Crushed iced was place vein and cannulated for perfusion. The duoc duodenojejunal junction. The small bowel dissected free with a portion of the diaphragi distal to the SMA. The liver and pancreas w	In and the aorta was exposed at the hiatus. The portal vein was exposed and the neuring enough length for both grafts. The patient was then fully do annulated. In conjunction with other retrieval teams, perfusion with UW add on the liver, pancreas and kidneys. A venotomy was made in the portal fenum was then divided with a GIA stapler just distal to the pylorus and at the searchey with SAW and SAW Awas divided using a GIA stapler. The liver was m. The IVC was divided above the renal veins. The aorta was divided just ere removed en blob. Perfusion to the kidneys was then re-established by identifying the ureters, the illiac arteries and veins were removed. A portion ere removed for HLA typing.			
ADDITIONAL NOTES				
Aberrant Vessels				
Aperiality Coocio.				



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Exhibit 2: DCD Liver/Kidney/Pancreas Retrieval Operative Note

16	NT DROOPAN CSF-9-47
UNIVERSITY OF TORONTO LIVER TRANSPLA	NT PROGRAM
DCD LIVER/KIDNEY/ PANCREAS RETRIEVA	L OPERATIVE NOTE
Hospital: Date:	
Patient Name: Medical Re	cord Number:
Surgeons:	
As per routine, the donor is givenof heparin in the ICU. After the withdraw of witnesses the cessation of ventilation and circulation for a pre-determined time period donor is transferred to the OR, prepped and draped in the usual sterile fashion. A mit notch down to the pubic bone. The abdominal cavity was entered, the intestines retret he Inferior Vena Cava (IVC) and abdominal was incised. The distal aorta was encirc immediately and the IVC opened anteriorly.	After this pre-determined time, the fline incision was made from the sternal cted medially, and the peritoneum over
The crura of the disphragm were divided and the supraceliac aorta was clamped and was placed on the liver and both kidneys.	the cold perfusion started. Crushed ice
The common bile duct was identified and divided distally; the gallbladder was opened clear fluids were coming out from the common bile duct.	and irrigated with saline solution until
After adequate cold perfusion of the porta hepatic, cold dissection was started first by and then dividing the gastrodoudenal artery. Dissection continued through to the celling the left gastric artery dissected and preserved, and the small branches to the lesser of to preserve an aberrant left hepatic artery). The dissection of the celiac trunk continuations under the portal vein was dissected distally and divided.	ac trunk, the splenic artery was divided, survature of the stomach were divided
Posterior to the pancreas, dissection of the superior mesenterio artery was carried or down to the sorts (to preserve an aberrant right hepatic artery). After identifying and it he sorts was opened anteriorly, divided posteriorly and split into both sides just abov was dissected up to the left renal vein. The left renal vein was divided with a cuff of the sort was divided with a cuff of	securing the origin of both renal arteries re the renal arteries. The distal aorta
The right atrium was divided distally to get the supra hepatic IVC and the infra hepati the right renal vein and it was divided above the renal vein.	c IVC was dissected until the origin of
The left triangular ligament of the liver was divided and the diaphragm incised bilater then the liver was removed with a patch of the diaphragm and portion of the right adm	
The pancreas was dissected out of the surrounding tissues, the duodenum was stable whole transplant or islet transplant.	ed then the pancreas was removed for
After identifying the ureters and renal vessels on both sides, both kidneys were disses and removed with the sortic patch. On the sterile back table each kidney was dissect and to exclude abnormal pathology.	
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 count.	insuring correct sponge and instrument
Additional Notes	
Aberrant Vessels:	
Organs Retrieved:	
Other:	
Signature:	
Immum: 25, 2028	



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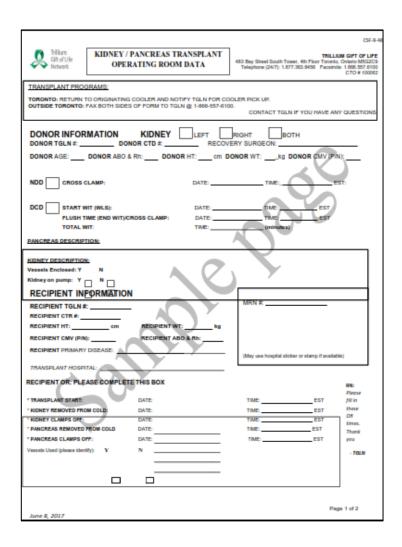
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Exhibit 3: Kidney/Pancreas Transplant Operating Room Data

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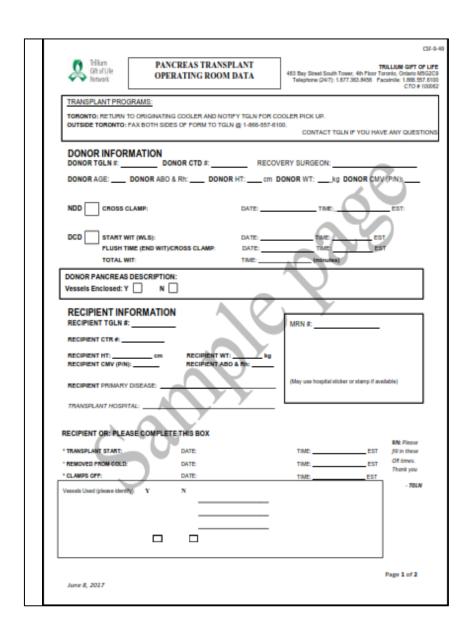
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Exhibit 4: Pancreas Transplant Operating Room Data

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Exhibit 5: Pancreas For Islets Transplant Operating Room Data

Gift of Life Network	PANCREAS FOR ISLETS TRANS OPERATING ROOM DATA			TRILLIUM GIFT OF r, 4th Floor Toronto, Ontario M 8.8456 Facsimile: 1.866.557. CTO # 10
RANSPLANT P	PROGRAMS:			
	IRN TO ORIGINATING COOLER AND NOTIFY T			
UTSIDE TORON	ITO: FAX BOTH SIDES OF FORM TO TGLN @ 1	-866-557-610		YOU HAVE ANY QUESTIC
DONOR I	NFORMATION			
DONOR TO	LN #: DONOR CTD #:		RECOVERY SURGEON	N:
DONOR AGE:	DONOR ABO & Rh: DONOR	HT:em	DONOR WT: kg DO!	NOR CMV (P/N):
NDD	CROSS CLAMP:	DATE:	TIME:	EST
	RETRIEVAL TIME:	DATE:	TIME:	EST
DCD	START WIT (WLS):	DATE:		EST
_	FLUSH TIME (END WIT)/CROSS CLAMP	DATE:	TIME:	EST
	TOTAL WIT:		(minutes)	
	RETRIEVAL TIME:	DATE:	TIME	: EST
Perfusion/Stora	ge Solution Manufacturer:	Lot #	Expir	y Date:
	Donouses for Islate to be etc	and at tom	nonotones of <00 100	
RECEIVING II	Pancreas for Islets to be sto			IME: EST
RECEIVING II	ATION OF DELIVERY: ISLET LAB INSTITUTION: STAFF:		peratures of <0°- 10°	IME:EST
RECEIVING II ACCEPTING SIGNATURE: RECIPIENT	ATION OF DELIVERY: ISLET LAB INSTITUTION: STAFF: INFORMATION			IME:EST
RECEIVING II ACCEPTING SIGNATURE: RECIPIENT TO	ATION OF DELIVERY: ISLET LAB NSTITUTION: STAFF: INFORMATION GLN #:			
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RECEIVING II ACCEPTING SIGNATURE: RECIPIENT TO RECIPIENT TO RECIPIENT CO RECIPIENT CO	TION OF DELIVERY: ISLET LAB NSTITUTION: STAFF: INFORMATION GLN #: ITT #: ITT: CM RECIPIENT WT: RECIPIENT ABO	DATE		
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