

Clinical Process Instruction Manual

Documentation: Donor Operating Room Process Instruction

Policy:

In order to facilitate tracing and meet Health Canada requirements, Trillium Gift of Life Network (TGLN) has developed and established mechanisms for documentation of donor information required for organ recovery. The records indicate the TGLN identification number, dates, times and locations of Instructions, and the individuals performing them.

Process:

1. The Clinical Services Coordinator (CSC) may complete the *Reporting Form: Clinical Services Coordinator to Surgical Recovery Coordinator* and discusses the information with the Surgical Recovery Coordinator (SRC) or designate prior to departure for donor hospital.
2. The CSC provides the appropriate “*Organ Specific*” *Recipient Transplant Operating Room Data* to the SRC or designate.
3. The SRC prepares all materials, forms and supplies.
4. The CSC provides a hard copy of the donor ABO report, and serology report to the SRC or designate.
5. The CSC provides a copy of any human leukocyte antigen (HLA) or specimen requisition to the SRC or designate if required.
6. If applicable, the CSC notifies the SRC or designate that organs are being released under exceptional distribution criteria and the reason for this application.
7. In the OR, the SRC or designate completes the Package Insert called the *Organ Donor Surgery Information* form, *CSF-9-57 (ODSIF)*. See Exhibit 1. If applicable, the SRC or designate documents the reason for exceptional distribution on the *ODSIF*.
8. Out of Province (OOP) donors: SRCs must complete *the ODSIF*, document OOP staff involved in recovery, and obtain their supply list ahead of time. If the complete supply list is unattainable, key supplies should be recorded, at a minimum.
9. The SRC or designate ensures that copies of the *ODSIF*, ABO, and serology accompany all organs.

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10. The SRC or designate advises the surgical fellow to complete the “*Organ Specific*” *Retrieval Operative Note* and to leave it in the hospital donor chart.
11. The SRC or designate completes any additional specimen requisitions and delivers specimens to the appropriate labs. The SRC or designate provides copies of requisitions for the donor chart.
12. The SRC or designate fully completes the supply list in the donor chart. In the event the donor chart is inaccessible, the SRC or designate fully completes the *Surgical Supply and Reagent Log, CSF-9-58* and adds it to the donor chart. See Exhibit 2. In the event more than one SRC or designate is present on a case, a minimum of one SRC or designate is required to sign-off on the supply list on behalf of the supplies used by other SRCs or designates.
13. The SRC or designate files a copy of the *ODSIF* in the TGLN donor chart.
14. The SRC or designate enters any remaining information from the *ODSIF* into the TGLN donor chart.

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
“Organ Specific” Retrieval Operative Note	—	Hospital donor chart	Hospital donor chart	As long as they require
“Organ Specific” Transplant Operating Room Data	—	PRC	PRC	16 years
Surgical Supply and Reagent Log	CSF-9-58	PRC	PRC	16 years

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References:

- *Exceptional Distribution Process Instruction, CPI-9-217*
- *Basic Safety Requirements for Human Cells, Tissues and Organs for Transplantation. Requirements, Guidance Document, Health Canada, July 2005*



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Exhibit 1: Organ Donor Surgery Information Form (ODSIF)

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ORGAN DONOR SURGERY INFORMATION

483 Bay Street, South Tower, 4th Floor Toronto, Ontario M5G 2C9
 Telephone (24/7): 1.888.603.1399 Facsimile: 1.866.557.6100
 CTO Registration #: 100062

CSF-9-57

** Indicates Health Canada Required Fields Note: Times are Eastern Time Zone

**TGLN #:		DOB: DD/MM/YYYY		CTD/Alternate #: OPTIONAL		**ABO+RH:	
**DATE OF RETRIEVAL:		DD/MM/YYYY		**RETRIEVAL HOSPITAL:			
OR ENTER TIME:		HH:MM		**ADDRESS:			
DONOR ENTER OR:		HH:MM					
SKIN CLUT TIME:		HH:MM					
OR EXIT TIME:		HH:MM		**PHONE NUMBER:			

INTRA-OP PROFILE / VITAL SIGNS (IF APPLICABLE. N/A if left blank):					
Rx	Dosage	Time	B/P	HR	O ₂ Saturation
COMMENTS:					

ORGAN PERFUSION DATA			
HEPARIN ADMINISTERED	Units: _____	Date: DD/MM/YYYY	Time: HH:MM
<input type="checkbox"/> NDD		<input type="checkbox"/> DCD	<input type="checkbox"/> NPOD
** Cross Clamp:	Date: DD/MM/YYYY	Time: HH:MM	W/ST: Date: DD/MM/YYYY Time: HH:MM
			**Arrest: Date: DD/MM/YYYY Time: HH:MM
			Flush: Date: DD/MM/YYYY Time: HH:MM

ORGAN(S) RECOVERED AND FLUSHING INFORMATION: (Note 1: Anatomy is normal unless stated below. Note 2: Fields below left blank are N/A)							
**Organ	Recovery Surgeon	**Flush Solution	Flush Sol. Vol. (L)	**Storage Solution	Storage Sol. Vol. (L)	**Cold Storage Time	**Anatomy / Comments
<input type="checkbox"/> Heart		<input type="checkbox"/> Celsior <input type="checkbox"/> Cardioplegia		<input type="checkbox"/> Celsior <input type="checkbox"/> Cardioplegia		HH:MM HH:MM	
<input type="checkbox"/> Lung		<input type="checkbox"/> Perfadex <input type="checkbox"/> (Retro) <input type="checkbox"/> (Ante)		<input type="checkbox"/> Perfadex		HH:MM HH:MM	
<input type="checkbox"/> Liver				<input type="checkbox"/> HTK <input type="checkbox"/> UW <input type="checkbox"/>		HH:MM HH:MM	
<input type="checkbox"/> Pancreas		<input type="checkbox"/> HTK <input type="checkbox"/> UW	(Aortic)	<input type="checkbox"/> HTK <input type="checkbox"/> UW <input type="checkbox"/>		HH:MM HH:MM	
<input type="checkbox"/> Left Kidney			(Portal)	<input type="checkbox"/> MPS-1 <input type="checkbox"/> UW <input type="checkbox"/>		HH:MM HH:MM	
<input type="checkbox"/> Right Kidney				<input type="checkbox"/> MPS-1 <input type="checkbox"/> UW <input type="checkbox"/>		HH:MM HH:MM	
<input type="checkbox"/>						HH:MM HH:MM	

**ORGAN SAFETY	
<input type="checkbox"/> This/these organ(s) has/have been processed as per Health Canada and TGLN Requirements, and is/are considered SAFE FOR TRANSPLANTATION OR	
<input type="checkbox"/> This/these organ(s) are being released under EXCEPTIONAL DISTRIBUTION for not complying with Health Canada Regulations and/or TGLN requirements for the following reasons:	
Health Canada • _____ • _____ • _____ • _____	TGLN <input type="checkbox"/> Travel to/Lived in History with risk for: _____ <input type="checkbox"/> Recipients of organs from EXD donors within a year of transplant <input type="checkbox"/> Persons who received treatment for hepatitis C in the last 12 weeks, currently receiving treatment for hepatitis C or persons with a past diagnosis of hepatitis C for which treatment details are unknown <input type="checkbox"/> Other: _____
**ERROR, ACCIDENT, ADVERSE REACTION OR RECEIPT OF ORGAN CONCERNS	
If there are any adverse reactions, errors, accidents or concerns with the receipt of the organ (e.g. damage to packaging, the way the organ was packaged, information that accompanied the organ, etc.) please contact TGLN PRC at 1.888.603.1399.	

SRC Name: _____	Signature: _____
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Page 2 Not Required. Page 2 only required if Kidneys Recovered, Vessels Recovered, Tissue Donor and/or additional comments.

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Exhibit 2: Surgical Supply and Reagent Log

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SURGICAL SUPPLY AND REAGENT LOG					CSF-9-58
TGLN Case Identification #: _____					
Item	Qty. Used	Lot #	Expiry Date	Manufacturer	
CRITICAL CONSUMMABLES					
ALL ORGANS					
Y Perfusion Tubing (Transplant Cardiopegia Set)				Maquet Cardiopulmonary AG	
Transplant DCD Donor Perfusion Line				Maquet Cardiopulmonary AG	
Y Perfusion Tubing				CardioMed	
Slush				Baxter	
Slush				Baxter	
Abdominal / Chest Retractor				N/A	
ABDOMINAL					
GIA 60 Stapler				TYCO Healthcare	
GIA 60 Stapler Reload				TYCO Healthcare	
GIA 60 Stapler Reload				TYCO Healthcare	
24F Venous Return Catheter				Maquet	
24F Venous Return Catheter				Maquet	
F Venous Return Catheter				Maquet	
Organ Bags				CardioMed	
Organ Bags				CardioMed	
Large Organ Container				CardioMed	
Large Organ Container				CardioMed	
UW Solution (Beltar)				Bridge to Life	
UW Solution				Bridge to Life	
HTX 1L				Methapharm	
HTX 1L				Methapharm	
HTX 2L				Methapharm	
HTX 2L				Methapharm	
SPS 1L				Organ Recovery Systems	
SPS 1L				Organ Recovery Systems	
SPS 2L				Organ Recovery Systems	
KIDNEY PUMP BAG					
Perfusion Circuits				Organ Recovery Systems	
Perfusion Circuits				Organ Recovery Systems	
KPS-1 Solution				Organ Recovery Systems	
KPS-1 Solution				Organ Recovery Systems	
Cannula Coupler				Organ Recovery Systems	
mm Straight Cannula				Organ Recovery Systems	
mm Straight Cannula				Organ Recovery Systems	
Seal Ring (7x20)				Organ Recovery Systems	
Seal Ring (10x35)				Organ Recovery Systems	
mm Universal Seal Ring				Organ Recovery Systems	
mm Universal Seal Ring				Organ Recovery Systems	

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