

Clinical Process Instruction Manual

Organ and Composite Tissue Labelling and Re-Labelling Process Instruction

Policy:

Labels ensure that the transplant program receives the correct organ(s)/composite tissue and associated vessels. In addition, labelling prevents the occurrence of any incidents and delays related to misidentification of the organ/composite tissue. Health Canada has established labelling requirements for organs/composite tissue that are recovered and transplanted.

In the event that a label detaches or the content is incorrect, Trillium Gift of Life Network (TGLN) ensures that label is replaced or corrected, as appropriate.

If TGLN was not involved in the labelling of an organ/composite tissue, TGLN confirms and verifies the information with the sending facility prior to re-labelling the organ/composite tissue.

TGLN has established protocols for labelling/re-labelling organs/composite tissue and associated vessels for identification and tracking between recovery, transportation and delivery.

Process:

Labelling

Three labels are required for each organ/composite tissue for transplantation:

- interior label
- package insert
- exterior label

1. Interior label

- 1.1 All organs, composite tissue and vessels are identified by affixing the interior label, to the outside of the sterile packaging. See Exhibit 1.
- 1.2 The interior label must be legible and made of durable material to prevent labels from removal/loss.
- 1.3 The following information is contained on the interior label:
 - name of organ or composite tissue, and whether left or right side, if applicable
 - label completed by (signature of person completing the label)
 - the unique donor identification code and National ID # if applicable
 - ABO and Rh factor of the donor
 - “Biohazardous Infectious Material” symbol and designation (Yes or No)
 - statement “for Exceptional Distribution” if applicable

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- 1.4 The Surgical Recovery Coordinator (SRC) or designate completes the interior label in the operating room OR. The “Biohazardous Infection Material” symbol shall be designated as “Yes” if there is a presence of an infectious disease (i.e. positive serology for HIV I/II, HCV, HBsAg, HBcAb IgM or IgG, HTLV I/II, Syphilis, WNV).
- 1.5 The SRC or designate ensures all organs and composite tissues are labelled appropriately. For kidney recovery, the SRC will verbally confirm with the Surgeon which side Kidney (i.e. Left kidney in Left Jar) is being placed in each jar.
- 1.6 When a plastic container is used, the SRC or designate shall ensure the label is affixed to the smooth side of the container on the outside of the 3rd layer of protection where possible.

2. Package insert

- 2.1 The following information must be contained in the package insert:
 - name of organ or composite tissue and whether left or right side, if applicable
 - description of organ or composite tissue if any abnormalities are noted
 - donor identification code and National ID # if applicable
 - all information in the donor assessment that is not capable of identifying the donor which includes: donors date of birth (DOB)
 - ABO group and Rh factor of donor
 - date and time of asystole or aortic clamping
 - date, time and time zone of retrieval
 - information specific to retrieval procedure
 - name of perfusion solution
 - name of storage solution
 - statement that the organ or composite tissue has been declared safe for transplantation
 - statement “for Exceptional Distribution”, if applicable
 - if applicable, the reasons for exceptional distribution & statement of how the organ or composite tissue does not meet the requirements of these regulations
 - instructions on how to report errors, accidents and adverse reactions
 - name of retrieval establishment, its civic address and contact information
 - name of source establishment, its civic address and contact information, and registration #
- 2.2 The SRC or designate is responsible for ensuring the package insert is included with each organ or composite tissue recovered.

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3. Exterior label

3.1 The exterior label is clearly identifiable on all organ coolers and should include:

- name of organ or composite tissue and whether left or right, if applicable
- a “Biohazardous Infectious Material” symbol and designation (Yes or No)
- name of retrieval establishment, its civic address and contact information
- name of source establishment, its civic address and contact information
- registration number of source establishment clearly labelled as such
- name of transplant establishment, its civic address and contact information
- statement “Human Organ/Composite Tissue for Transplant”
- handling instructions for storage and for storage during transplantation

The SRC or designate is responsible for ensuring an exterior label is present and complete for each organ recovered. The “Biohazardous Infection Material” symbol shall be designated as “Yes” if there is a presence of an infectious disease (i.e., positive serology for HIV I/II, HCV, HBsAg, HBcAb IgM or IgG, HTLV I/II, Syphilis, WNV). See Exhibit 2.

Re-labelling

4. Prior to Organ Delivery

4.1. In the event that an error is recognized on any of the labels, the SRC or designate revises the label as per *Making Error and Information Corrections Process Instruction, CPI-9-806*. If due to space limitations a new label is required, the SRC or designate strikes through the incorrect portion of the original label and staples the new, accurate label onto it.

4.2. The SRC or designate makes a note on the *Organ Donor Surgery Information* to document the re-labelling and/or error correction.

5. Following Organ Delivery

5.1. If a transplant program notifies Provincial Resource Centre (PRC) that the interior label is missing or incorrect, the Clinical Services Coordinator (CSC) makes arrangements to have the Coordinator who originally labelled the organ/composite tissue go on-site. If the original Coordinator is unavailable or unable to go on-site, the CSC verbally verifies the information with them. The CSC makes a note in the clinical notes.

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- 5.2. If able to go on site, the dispatched Coordinator reviews the labelling and supporting documentation if available. The Coordinator re-labels and/or corrects the label if they can verify the donor identification number and other relevant information. If a Coordinator is not able to go onsite due to geography, the CSC discusses the situation in a huddle with the MOC and Coordinator who originally labelled the organ/composite tissue and Transplant Support Physician (TSP) if required.
- 5.3. If no documentation is available with the organ/composite tissue (e.g. package inserts, etc.), and accordingly the Coordinator is unable to confirm the donor identification number of the organ/composite tissue, the CSC contacts the TSP to determine whether the organ and/or composite tissue should be re-offered using exceptional distribution protocols and documents this in the clinical notes of the donor assessment. See *Exceptional Distribution Process Instruction, CPI-9-217*.

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Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Interior Label	CSF-9-60	Recipient Hospital	Recipient Hospital	As long as they require
Exterior Label	CSF-9-59	Recipient Hospital	Recipient Hospital	As long as they require
Organ Donor Surgery Information	CSF-9-57	PRC	PRC	16 years
Assessment Form: Organ/Combined Organ and Tissue Donor	CSF-9-15	PRC	PRC	16 years
Assessment Form: Tissue Donor	CSF-9-16	PRC	PRC	16 years

References:

- *Guidance Document for Cell, Tissue and Organ Establishments Safety of Human Cells, Tissues and Organs for Transplantation, Health Canada*
- *Donor Assessment Process Instruction, CPI-9-208*
- *Exceptional Distribution Process Instruction, CPI-9-217*
- *Organ/Composite Tissue Labelling Process Instruction, CPI-9-417*
- *Making Error and Information Corrections Process Instruction, CPI-9-806*
- Canada Gazette. Safety of Human Cells, Tissues and Organs for Transplantation Regulations. Vol. 141, No. 13, Pages 1216 – 1707



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Exhibit 1: Interior Label

CSF-9-60

<p>TRILLIUM GIFT OF LIFE NETWORK // Reg. # 100062 483 Bay Street South Tower, 4th Floor Toronto, Ontario M5G 2C9 Phone: 416.363.4438 // 1.877.363.8456</p> <p>TGLN ID # _____ Donor Blood Type & Rh: _____</p> <p>National ID # (if applicable) _____</p> <p>Organ/Composite Tissue: _____ (Circle) L R</p> <p>Date of Birth: _____ (circle): Yes No</p> <p>Exceptional Distribution: (circle): Yes No</p> <p>Organ/Composite Tissue Label Completed By: _____</p>	<p>TRILLIUM GIFT OF LIFE NETWORK // Reg. # 100062 483 Bay Street South Tower, 4th Floor Toronto, Ontario M5G 2C9 Phone: 416.363.4438 // 1.877.363.8456</p> <p>TGLN ID # _____ Donor Blood Type & Rh: _____</p> <p>National ID # (if applicable) _____</p> <p>Organ/Composite Tissue: _____ (Circle) L R</p> <p>Date of Birth: _____ (circle): Yes No</p> <p>Exceptional Distribution: (circle): Yes No</p> <p>Organ/Composite Tissue Label Completed By: _____</p>
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Exhibit 2: Exterior Label

SOURCE ESTABLISHMENT			
 <input type="checkbox"/> TRILLIUM GIFT OF LIFE NETWORK 24 / 7 - 1-877-363-8456 / (416) 363-4438 483 Bay Street South Tower, 4 th Floor Toronto, Ontario M5G 2C9 CTO # 100062		<input type="checkbox"/> Other: _____ _____ CTO# _____	
HUMAN ORGAN/COMPOSITE TISSUE FOR TRANSPLANT Handle with Care Keep Cool – Do Not Freeze  YES <input type="checkbox"/> NO <input type="checkbox"/>		Vessel Type: Iliac <input type="checkbox"/> Carotid <input type="checkbox"/> Other: _____ <input type="checkbox"/> ORGAN/COMPOSITE TISSUE: _____ (Circle): L R Retrieval Establishment: _____ Address: _____ Contact Number: _____	
TRANSPLANT ESTABLISHMENT			
<input type="checkbox"/> Toronto General Hospital 200 Elizabeth Street Toronto, ON M5G 2C4 (416) 340-3405	<input type="checkbox"/> Toronto Western Hospital 399 Bathurst Street Toronto ON M5T 2S8 (416) 603-5744	<input type="checkbox"/> Hospital For Sick Children 555 University Avenue Toronto, ON M5G 1X8 (416) 813-7500	<input type="checkbox"/> St. Michael's Hospital 30 Bond Street Toronto, ON M5B 1W8 (416) 864-5901
<input type="checkbox"/> St. Joseph's Hospital 50 Charlton Avenue E Hamilton, ON L8N 4A6 (905) 522-1155	<input type="checkbox"/> London Health Sciences Centre – University Hospital 339 Windermere Road London, ON N6A 5A5 (519) 663-3060	<input type="checkbox"/> Kingston General Hospital 76 Stuart Street Kingston, ON K7L 2V7 (613) 548-7820	<input type="checkbox"/> The Ottawa Hospital – General Campus 501 Smyth Road Ottawa, ON K1H 8L6 (613) 737-8409
<input type="checkbox"/> The University of Ottawa Heart Institute 40 Ruskin Street Ottawa, ON K1Y 4W7 (613) 761-4708		<input type="checkbox"/> Other: _____ _____ Contact Number:() _____ - _____	
SOURCE ESTABLISHMENT			
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