Ontario
Trillium Gift of Life Network

Clinical Process Instruction Manual

Heart Valves – Combined Organ/Tissue Case Process Instruction

Policy:

Trillium Gift of Life Network (TGLN) will work in collaboration with The Hospital for Sick Children's (HSC) Tissue Laboratory to facilitate recovery of hearts for valves as required. In most cases, recovery of heart for valves occurs following the recovery of the liver and/or lungs.

Aseptic technique and sterility are adhered to during recovery. TGLN accepts basic hospital Operating Room (OR) standards for preparation of surgical room, the donor and sterility of instrument sets for multi-organ recovery.

TGLN and HSC will only proceed with recovery of heart valves if the appropriate consent and donor screening testing has been obtained.

This process instruction only applies if a Surgical Recovery Coordinator (SRC) is involved in the recovery for heart valves.

Process:

Prior to Departure to Recovery Hospital

1. The TGLN Coordinator arranges for the organ recovery team to retrieve the heart for valves on behalf of the HSC Tissue Laboratory, if organ recovery is to occur.

2. The TGLN Coordinator notifies the SRC or designate of the impending heart valve case.

3. The SRC or designate ensures that the retrieval kit is prepared with the following items:
    - *Heart Valve Retrieval Form* (See Exhibit 1)
    - *Heart Valve Recovery Note (*See Exhibit 2*)*
    - Donor blood sample labels
    - 1 Red top
    - 2 EDTA tube
    - 2 non-sterile plastic envelopes
    - 1 organ label or equivalent
    - 1 large organ container or equivalent sterile container
    - 2 CardioMed organ bags or equivalent sterile bags
    - 1 1000 ml bottle of Tis-U-Sol1 validated red Styrofoam cooler or equivalent transport cooler
    - 1 white lock or equivalent
    - 2 bags of sterile slush

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- **For HV recovery on Lung Transplant Donors only:**
  - 1 x 1000 ml Normal Saline1 x a CardioMed organ bag or equivalent sterile bag (e.g. Steri-Drape Isolation Bag)

At the Recovery Hospital

4. Upon arrival in the OR, the SRC or designate confirms the donor's identification.

5. The SRC or designate ensures that blood samples (2 EDTA and 1 Red top) are obtained and labelled. The SRC or designate double checks that the label includes the TGLN identification number, donor date of birth, and the date and time of blood collection.

6. The SRC or designate fills out the appropriate information on the *Heart Valve Retrieval Form*. Additionally, if information is available, the SRC or designate checks that the instrument sets have been sterilized records the Lot # of the instrument sets and expiration date of all supplies related to the heart recovery.

7. Upon examination of the OR set-up, the SRC or designate asks the circulating staff for a large sterile basin, 1L bottles of normal saline, and an extra sterile table if required.

8. The SRC or designate proceeds to prepare the sterile field for the packaging of the heart for valves by ensuring packaging integrity, then opening the 1L plastic container and 2 of the plastic bags and placing them near the edge of the sterile table. The sterile basin is passed into the field and filled with 2L of crushed sterile slush.

9. As the SRC or designate scrubs out, approximately a minimum of 500 ml of the Tis-U-Sol solution is added to the large organ container or equivalent, and 1L of sterile normal saline is added to the large basinof slush to complete the packaging table. Note: All solutions should remain on ice until the rinsing and packaging procedure is close to commencing.

10. Upon completion of cross-clamp and perfusion of the other organs, the SRC or designate advises the Recovery Surgeon to procure the heart and as much pericardium as possible by cutting the ascending aorta and the superior vena cava. The SRC or designate informs the Recovery Surgeon that the HSC requires that the pericardium pieces be at least 60mm x 60mm in size.

11. The Recovery Surgeon is advised to place the heart in the bowl and massage the heart gently to introduce the liquid into the chambers of the heart. The heart should then be gently inverted to drain the fluid.

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12. The SRC or designate advises the Recovery Surgeon to completely submerge the heart into the plastic container filled with Tis-U-sol and to secure the lid tightly to prevent leakage and contamination. The SRC or designate advises the Surgeon to place the container in a plastic bag and securely tie the bag, and to repeat with a second bag.

13. The SRC or designate places an organ label on the package as per *Organ and Composite Tissue Labelling Process Instruction, CPI-9-417.* The three tubes of labelled donor blood are placed in a biohazard bag and left in the red cooler.

14. The SRC or designate fills the red Styrofoam cooler or equivalent with ice and places the tissue inside, completely covering the tissue with ice, ensuring that the heart valves remain sterile and at a suitable temperature throughout transport.

15. The SRC or designate reviews the *Heart Valve Retrieval Form* for completeness and inserts the completed form and any other pertinent documentation (See *Documentation: Donor Operating Room Process Instruction, CPI-9-416*) into the plastic envelope located on top of the cooler. The cooler is sealed using a white lock or equivalent to prevent tampering during transport from the recovery site to HSC Tissue Laboratory.

16. Prior to departing the recovery hospital, the SRC ensures a copy of the *Heart Valve Recovery Note* is completed, signed by the appropriate surgical staff, and left in the hospital donor chart.

17. Following the completion of the case, the SRC or designate makes arrangements for the cooler to be dropped off at the HSC Tissue Laboratory or Blood Transfusion Laboratory (3rd floor, New Atrium).

For HV recovery on Lung Transplant Donors

18. Follow steps number 4, 5 and 10.
19. The Recovery Surgeon or designate will place the heart and pericardium in a CardioMed organ bag or equivalent sterile bag (e.g. Steri-Drape Isolation Bags).
20. The Recovery Surgeon or designate will fill the sterile bag with1 L of sterile saline to completely submerge the heart and pericardium. The sterile bag is tied and closed securely to prevent leakage and contamination. The packaged heart and pericardium are then placed into the chest cavity. The SRC or designate documents the date-time heart was recovered.

21. The SRC or designate ensures the three tubes of labelled donor blood are placed in a biohazard bag and left with the donor's body to be collected by the multi tissue coordinator (MTRC) or multi tissue recovery team.

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22. The SRC or designate informs the PRC regarding the completion of the case.

22. Completion of rinsing, re-packaging and labelling of the recovered heart as per Cardiovascular Tissue Recovery Process Instruction (CPI-9-527) will be performed as soon as the multi tissue recovery coordinator (MTRC) or multi tissue recovery team arrives at the hospital.

Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Heart Valve Retrieval Form	CSF-9-82	PRC	PRC	16 years

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Heart Valve Recovery Note	CSF-9-81	PRC	PRC	16 years

References:

- *Perfusion & Packaging: Heart Process Instruction, CPI-9-408*
- *Documentation: Donor Operating Room Process Instruction, CPI-9-416*
- *Organ and Composite Tissue Labelling Process Instruction, CPI-9-417*
- *Organ Re-Labelling Process Instruction, CPI-9-418*
- Organ Label

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Exhibit 1: Heart Valve Retrieval Form

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CSF-9-82

Trillium Gift of Life Network

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Patient Identification

Heart Valve Retrieval Form

Donor Information

TGLN Number: _____
Last name: _____
First name: _____
Birth Date: _____ dd/mm/yy
Retrieval Hospital: _____

Type of donor: ☐ NDD ☐ DCD

Retrieval Environment:
☐ O.R. ☐ Other: _____

Donor identified by:
☐ Wrist Band ☐ Toe Tag ☐ Other: _____

Donor ID & Consent Verification: Before retrieval, it was confirmed that consent for the tissue donation was verified and documented. The name on the consent, medical chart and the donor's ID match.

Name of Person Verifying Donor ID and Consent:
_____

Pre-Recovery Assessment	**Yes**	**No**
Adequate floor and tabletop space to allow separation of sterile instrumentation and performance of aseptic recovery procedures (i.e., zone recovery, sequencing, draping, tissue wrapping) is present.		
Adequate lighting to perform physical assessment and tissue recovery is present.		
Adequate plumbing and drainage for the intended purpose to include access to an adjacent or suitably located hand-washing area that can be used to perform a hand/forearm surgical scrub or wash is present.		
The recovery area has a controlled, closed airflow system. There is no direct access to the outside of the building from the room at any time during, before, or after tissue recovery. All vents appear clean and there is no vented airflow noted to be directed and flowing onto sterile fields.		
The walls, floor, and work surfaces are easily cleanable (i.e., non-carpeted, not porous) and in a good state of repair.		
Signs of insects, rodents, or other pests are not visible.		
Standing fluids or contaminated waste in the room, that could be a source of airborne bacteria, mycobacteria, yeasts or fungi, are not present.		
The recovery room was properly prepared by cleaning and disinfecting all working surfaces prior to recovery of tissue.		
Concurrent With Recovery	**Yes**	**No**
Human traffic is restricted and all personnel entering the recovery area are properly outfitted and their movement controlled.		
Other activities (e.g., embalming, autopsy, another tissue donor recovery) did not occur simultaneously in the same room as this tissue recovery.		

Comments: _____

The above parameters have been met and the recovery site has been determined to be suitable (check one):

Yes: __ No: ___ Signature: _____ Date: _____ Time: _____

Donor Physical Assessment NOTE: This document has already been completed and submitted to SickKids prior to the recovery coordination.

June 8, 2017

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Exhibit 2: Heart Valve Recovery Note

SickKids

The Hospital for Sick Children
Heart for Valves Recovery Note

Hospital: _____ Date: _____

Patient Name: _____ TGLN #: _____ MRN: _____

Recovery Personnel: Name, Affiliation, and Position

1. (Lead)_____
2. _____

The identity of the patient was confirmed along with the consent form and a physical examination of the patient was completed.

All in-situ IV lines, defibrillator pads, and tubes, etc. still attached to the patient were removed (in accordance with Coroner's directive, if applicable).

The chest, from the neck to the navel, was cleaned using a 70% alcohol solution and sterile gauze. A surgical scrub solution and sterile gauze were then used to further cleanse the area. Lastly, Povidone-Iodine swabsticks were used to apply antiseptic to the area.

A median sternotomy was made to enter the chest. The pericardium was opened and the heart was exposed.
A blood sample was collected from a chamber of the heart and transferred into tubes labeled with the patient information to be tested for infectious diseases.

The inferior vena cava was transected at the junction to the right atrium. The right pulmonary veins were transected as distally as possible. The right pulmonary artery was transected at the hilum. The superior vena cava and innominate vein were exposed and transected. The neck vessels, the brachiocephalic, left carotid, and left subclavian arteries were exposed distal to the take-off from the aortic arch and transected. The heart was retracted rightward and superiorly and left pulmonary veins and artery were transected as distal as possible. The aorta was transected distal to the ligamentum arteriosus, completing the retrieval.

A large piece of pericardium was recovered. ☐ **N/A**

If possible, the descending thoracic aorta was recovered by opening the left pleural space, resecting the lung medially and excising the aorta distal to the left subclavian artery. The intercoastal arteries were transected 3-4mm from the aorta and care was taken to avoid injuring the adjacent esophagus. ☐ **N/A**

The heart was placed in a sterile bowl filled with Ringer's lactate and gently massaged to introduce the liquid into the chambers of the heart. To drain the fluid, the heart was inverted gently. This rinsing process was repeated a second time with a new bag of Ringer's lactate.

The chest cavity was sutured closed and the patient was rewrapped in the shroud and returned to the storage location from which was retrieved.

Signature (Lead Physician): _____ Date: _____

May 21, 2014