Development of a platform for ex vivo heart perfusion REVISED RESEARCH PROFILE

Background

Brief Description of Program: This is a prospective study to develop an Ex-Vivo Heart Perfusion (EVHP) System designed for biventricular assessment and evaluation. Hearts, from donors that have been consented for research and declined for transplant and heart valves, will be used in the development of a clinical model to evaluate cardiac function and improve our ability to preserve hearts through the use of normothermic EVHP. The ultimate goal is to expand the donor pool and reduce the waitlist for heart transplantation. The study will require 200 hearts for the biobank and 20 hearts for the ex vivo heart perfusion.

Program: Toronto General Hospital, University Health Network

Contact Person(s) & Contact Information:

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Offering Information:

Hearts will be offered out (including for heart valves) and if rejected, TGLN will offer the heart to the TGH MOTC for research. TGH MOTC will communicate offer to the research team and respond to TGLN. TGH MOTC will communicate recovery timing details to the research team.

Inclusion:

- 1. Ontario NDD or DCD donors (at least one organ is being recovered for transplant) whose hearts and heart valves are rejected for transplant at the time of offering.
- 2. Recovery site must be 2 hours or less of travel (car) time from UHN.
- 3. UHN team is participating in the recovery of an organ other than the heart.
- 4. Donors must be 18 to 65 years old.

Recovery

COVID CONSIDERATIONS

Transportation: TGLN and transplant programs have worked together to limit the number of people travelling in each vehicle to allow spacing and minimize risk. Therefore, the UHN cardiac retrieval team will be required to arrange their own transportation.

Personal Protective Equipment: UHN cardiac retrieval team will supply their own N95 masks where applicable.

Method:

Recovery of the hearts will be done by the UHN cardiac/lung transplantation retrieval team. Hearts will be procured as per research protocol. Hearts will be flushed with 1 liter of Celsior solution, stored in cold saline, double bagged, in a cooler with ice for transport. Preparation of the heart block for either ex vivo perfusion or for storage will occur at UHN.

Recovery of blood will be done by the UHN cardiac/lung transplantation retrieval team:

- (1) For NDD cases, 1.5 to 2 L of blood may be recovered prior to cross-clamp in the OR.
- (2) For DCD cases, 1.5 to 2 L of blood may be recovered pre flush.

The SRC(s) will bring the routine supplies required for heart recovery. UHN cardiac/lung transplantation retrieval team will bring supplies specific to the ex vivo machine (bags, sterile transfusion line and puncture needle for collection of blood).

Requirements for Perfusion: Standard heart recovery.

Time Requirements: Standard heart recovery.

Impact on Transplant/ Recovery Procedure: None

Effect on Body / Post-Mortem Care: None

Consent Considerations:

DOES require research consent from the donor NOK for the heart.

Recovery Personnel:

UHN cardiac/lung transplantation retrieval team

Credentialing: As per PRC database.

Required Documentation:

Documentation: As per usual documentation