Trillium Gift of Life Network

Abdominal Normothermic Regional Perfusion

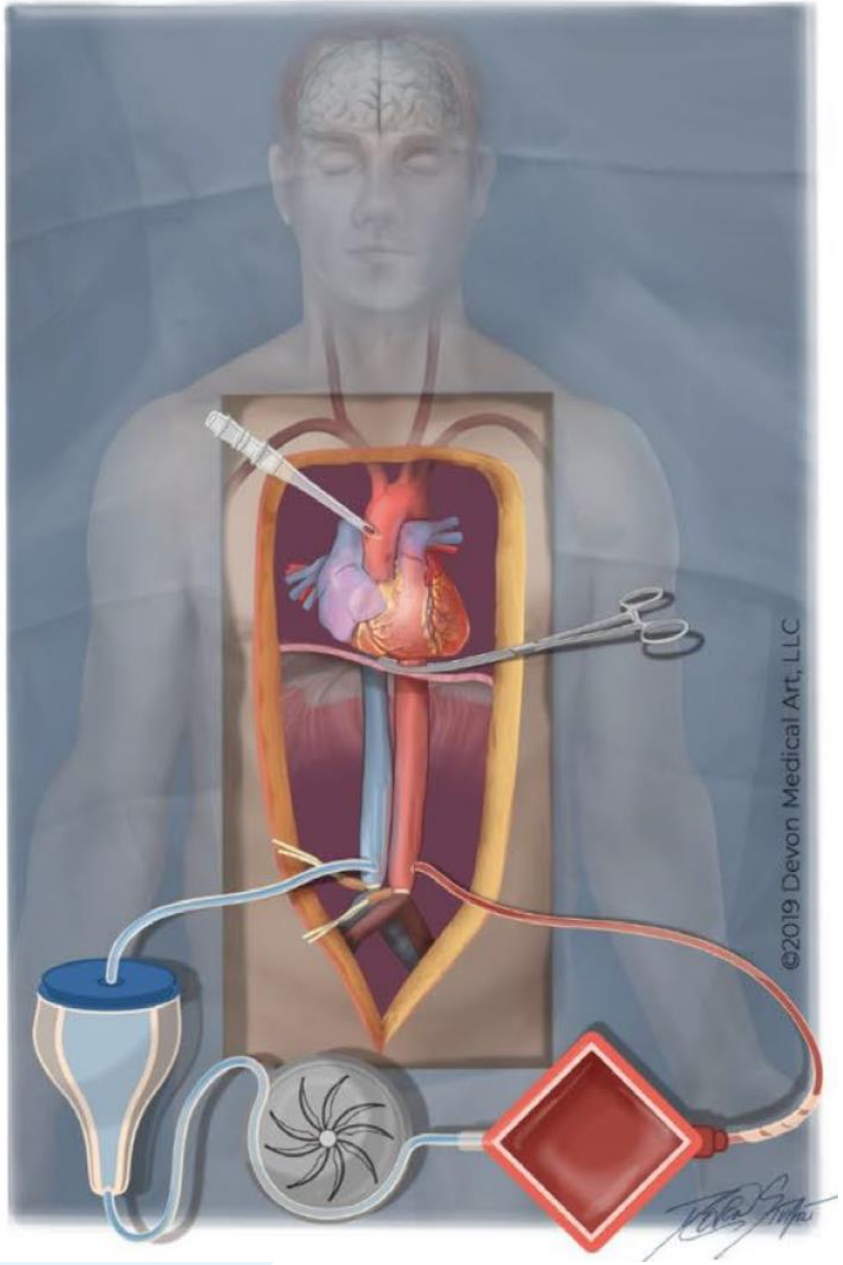
CONCLUDE Research Study
TGLN Staff Roles

April 4, 2024

Ontario Health

Overview of Protocol

- Abdominal Normothermic Regional Perfusion (A-NRP) is a novel post-mortem donor intervention that can increase the quantity and improve the quality of organs recovered from DCC donors.
- A-NRP involves post-mortem cannulation of donor's vasculature, connection to extra-corporeal circuit, and resumption of regional in situ normothermic circulation

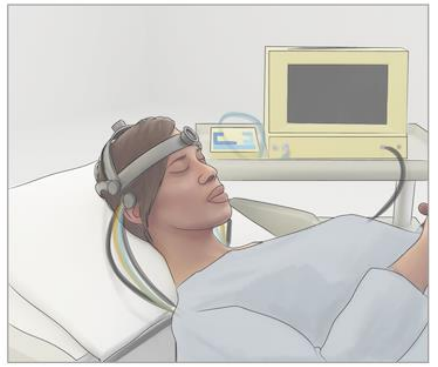


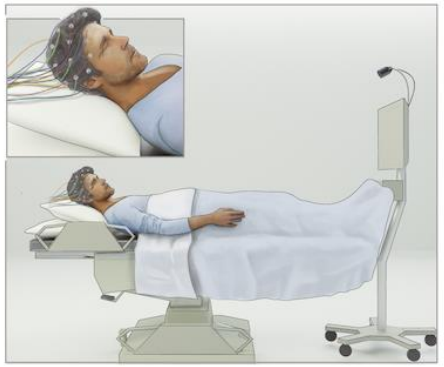
Background on A-NRP

- Employs extracorporeal membrane oxygenation (ECMO) to mechanically circulate oxygenated blood within a donor's body after death determination
- Not currently used in Canada
- Theoretical risk of resumption of brain activity or function if surgical safeguards are ineffective
- Confirming the permanent cessation of intracranial circulation during A-NRP is an important step toward the implementation of A-NRP in Ontario
- A-NRP research with this goal has been approved

Study Objectives

- **Study aim:** to assess if surgical safeguards successfully prevent the resumption of brain blood flow and activity during A-NRP in DCC donors.
- This will be done through multi-modal neuromonitoring during the dying process and throughout the A-NRP procedure.
- Confirmation of absence of intracranial blood flow will reassure the organ donation community and donor families that the use of a pump to circulate blood to the donor's organs does not lead to the resumption of brain blood flow, brain activity, or brain function in organ donors after they have died.





Staff Roles and Responsibilities

Practice Considerations

Notification and approach planning aspects of the donation process **do not change.**

After donation consent, and following acceptance of abdominal organs by participating transplant programs, **a research coordinator will approach** the substitute decision-maker/family of the patient to explain the study and obtain consent for study participation.

Withdrawal of life-sustaining measures (WLSM) and determination of death will **occur as per usual practice.**

<u>After consent, study activities by research personnel include:</u>

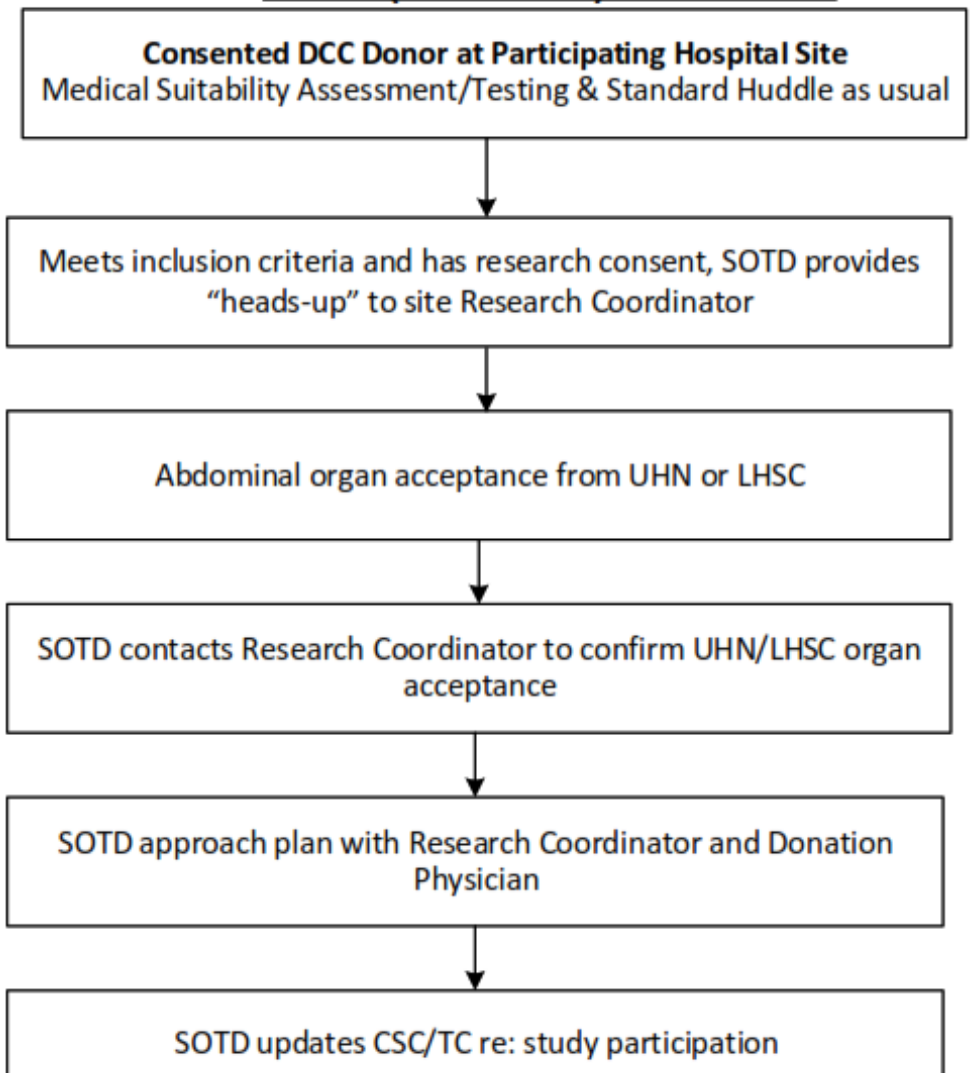
1. Application of neuromonitoring electrodes/probes and 10 min. assessment prior to WLSM
2. Post-mortem neuromonitoring device connection and assessment in OR
3. Post-mortem insertion of a canula for extracorporeal perfusion in the OR, and management of the perfusion (ECMO) pump used during A-NRP
4. A-NRP protocol intra-operatively for 1-4 hours prior to usual organ recovery

Inclusion Criteria/Exclusion and Candidate Identification

Participating Hospitals and Program

- London Health Sciences Center (University and Victoria sites)
- Toronto Western Hospital

A-NRP (CONCLUDE) Process Tree



Inclusion Criteria

- Potential DCC donors whose families/ surrogate decision makers have consented to DCC organ donation according to current criteria of the participating transplant programs
- DCC donors may include patients donating a liver, kidneys, pancreas, and/or lungs

Exclusion Criteria

- All first-person consent donors (MAID & WLSM)
- Registered Consent Decision of Transplant only
- Current injuries that anatomically preclude the use of neurological monitoring

Consent and Authorization

SOTD	• SOTDs obtain consent as per usual for DCC situation • research consent* as per usual • Provide Site Research Coordinator with “Heads up” • Once abdominal organ accepted by UHN or LHSC, contact Research Coordinator to confirm • Plan for introduction of Research Coordinator
Research Team	• Discussion with family CONCLUDE Research • Obtain Research Consent • Update SOTD
SOTD	• Update CSC and TC

*TGLN deceased donation consent documentation is required by SOTD

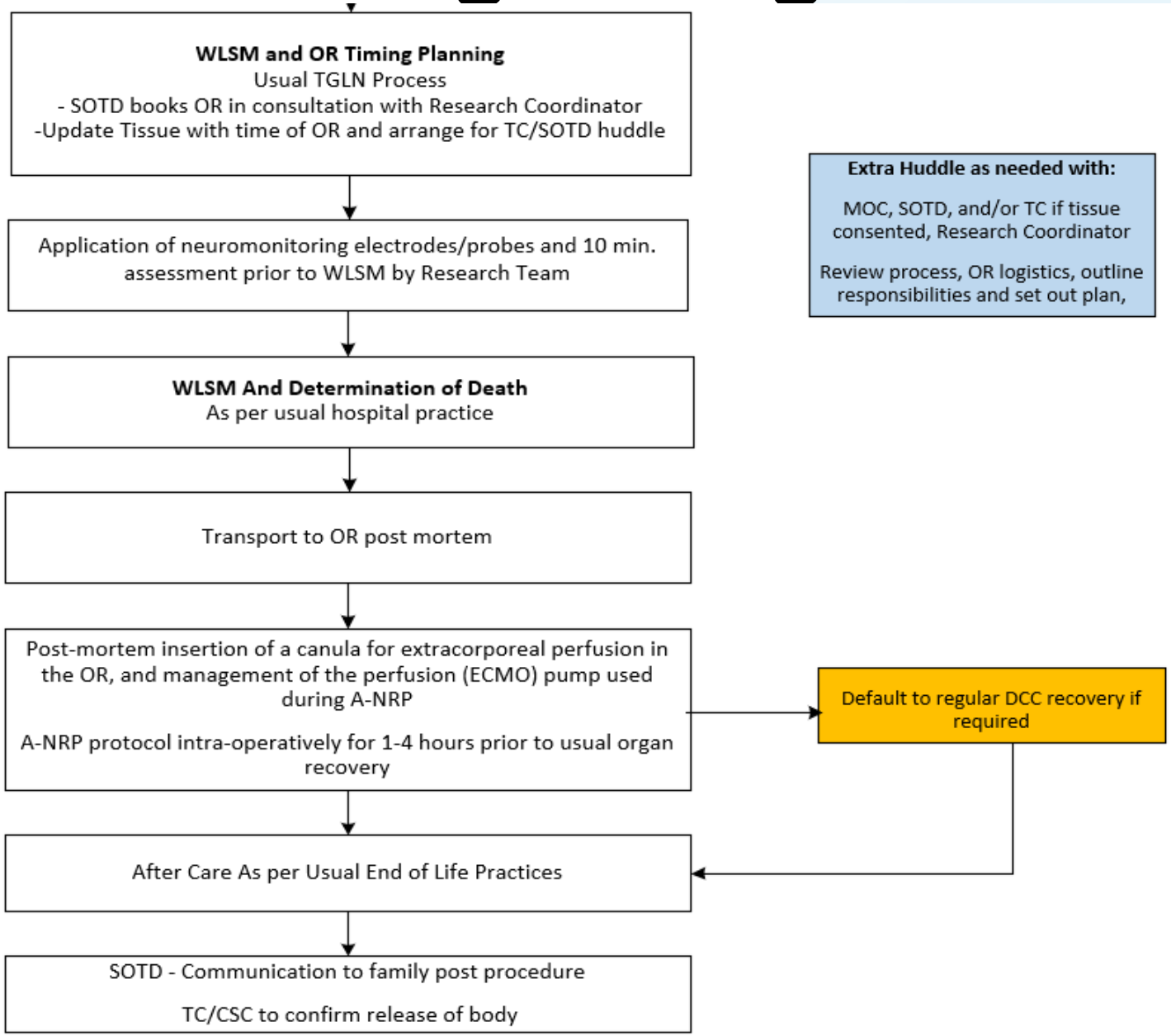
Huddle and MOC Report

CSC	• Runs huddle as per usual and ensure research is raised
SOTD	• Identifies consent for research obtained and potential research candidate pending acceptance • Confirms “heads up” to Research Coordinator was given
MOC	• Notes potential for research at UHN/LHSC cases on MOC report

Organ Offers

- Research representatives have presented at working groups in Ontario
- Dr. Slessarev consulting Dr. Treleaven regarding additional communication need, and out of province offers
- "*Ontario is working to implement A-NRP as part of our standard recovery, and right now we are doing a donor safety study to confirm the lack of blood flow to the brain. A-NRP may be used in the recovery of these lungs/liver/kidneys*"
  - Dr. Slessarev and Dr. Selzner will provide support regarding accepting program questions
  - *Informational brochure for recipients if requested*

Process from OR Planning through Recovery



OR Planning and WLSM

CSC	• Dr. Selzner will make an effort to recovery kidney-only cases at TWH (rather than SMH) to use NRP • OR planning with Transplant, Research Coordinator, hospital and family • Dr. Slessarev and Dr. Selzner will provide support regarding accepting program questions
SOTD	• Just in time education for hospital staff • OR planning with Transplant, Research Coordinator, hospital and family
Research Team	• Neuromonitoring pre-WLSM
SOTD	• Support family/relay VS as per usual DCC protocol • Update Tissue on timing of OR
MRP/ team	• WLSM as per hospital protocol • Death Determination as per DCC protocol
SRC	• Plan to bring extra sterile ice (ice needs to be prepared before WDLS if at any point they proceed with a traditional dcc recovery)

OR

SOTD	• Usual OR huddle • Ensure OR team aware of transition to rapid recovery vs ANRP if neuromonitoring issues a concern
Research Team	• Neuromonitoring attachment in OR post transfer and monitoring • Signal if need for default to usual recovery process
Surgical Team/OR team	• Rapid prep for cannulation
Transplant Team	• Perfusionist supplied by Transplant Team to set up and run the perfusion circuit (ECMO)
SRC	• Relay time points in real-time to CSC (as per usual practice). • Support case as usual • Participate in switch to usual recovery process if required

Post Recovery

SOTD	• Debrief with team • Communication to family as per agreed timing, SOTDs to focus on the outcome of the donation as per usual conversations with families after DCC.

If family asks if everything went well with the research.
Thank you again for agreeing to the research, this will help future recipients, although we can't share specifics of the research, please know that your loved one's participation has made a difference.

Why can't you tell me what happened with the research?
I know there was a lot of information shared when the Research Coordinator reviewed the study with you, but you may remember that they are going to take the recordings and analyze them as part of the whole study. The data from one participant, isn't enough to draw any conclusions from.

Did they have to stop the research and do the normal organ recovery?
I can tell you that the organs were able to be successfully recovered (and transplanted), or answer below if organs were not transplanted

Why weren't the organs transplanted, is it because of the research?
Every measure was put in place to ensure that the research didn't impact the donation or transplant of life-saving organs, as we discussed during the process, sometimes organs are not able to be recovered or used even if we plan for it.

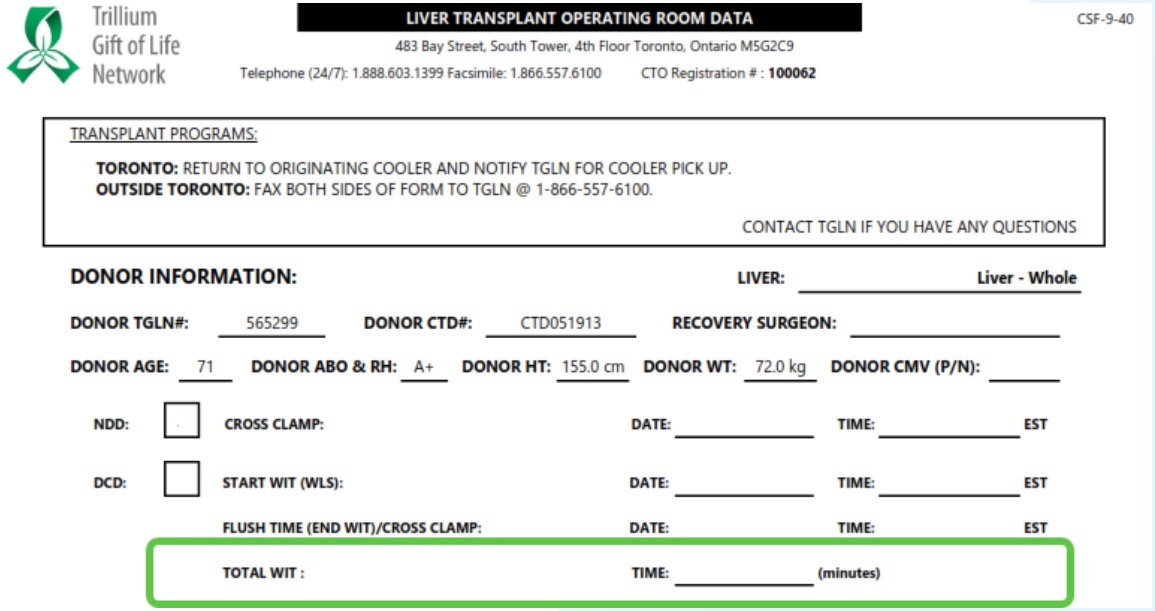
Documentation

SOTD	• SOTDs obtain consent as per usual for DCC situation with research option documented • Document notification of Research Coordinator post-organ abdominal acceptance by UHN/LHSC • Document communication of research consent outcome • Document communication of research consent outcome to CSC and TC (if applicable) • Document relevant OR planning considerations • Document research protocol “in progress” related to WLMS • Document Family advised of organ outcome post recovery
CSC	• Document relevant OR planning considerations specific to the research study (e.g. coordination of timing relayed by MOTC or TDS)
Team Lead	• Ensure research is noted on CSC report

Documentation cont'd

SRC	• Document the start and end time of NRP in the comments section of the ODSI (Relay time points in real-time to CSC as per usual practice)
TDS	• Document NRP start and end times in their Donor Surgery Form

Further details re: WIT calculation pending



Trillium Gift of Life Network

LIVER TRANSPLANT OPERATING ROOM DATA

CSF-9-40

483 Bay Street, South Tower, 4th Floor Toronto, Ontario M5G2C9

Telephone (24/7): 1.888.603.1399 Facsimile: 1.866.557.6100 CTO Registration # : **100062**

TRANSPLANT PROGRAMS:

TORONTO: RETURN TO ORIGINATING COOLER AND NOTIFY TGLN FOR COOLER PICK UP.
OUTSIDE TORONTO: FAX BOTH SIDES OF FORM TO TGLN @ 1-866-557-6100.

CONTACT TGLN IF YOU HAVE ANY QUESTIONS

DONOR INFORMATION: **LIVER:** Liver - Whole

DONOR TGLN#: 565299 **DONOR CTD#:** CTD051913 **RECOVERY SURGEON:**

DONOR AGE: 71 **DONOR ABO & RH:** A+ **DONOR HT:** 155.0 cm **DONOR WT:** 72.0 kg **DONOR CMV (P/N):**

NDD: ☐ **CROSS CLAMP:** **DATE:** **TIME:** **EST**

DCD: ☐ **START WIT (WLS):** **DATE:** **TIME:** **EST**

FLUSH TIME (END WIT)/CROSS CLAMP: **DATE:** **TIME:** **EST**

TOTAL WIT : **TIME:** **(minutes)**

Resources

A-NRP Family Resource Video Link Password = aNRP2024!

An A-NRP Resource Package will be made available on the ORC.

Questions

Thank you!