OPTN
Organ Procurement & Transplantation Network

OPTN Board of Directors Meeting

November 6, 2026



OPTN Normothermic Regional Perfusion (NRP) Policy

PJ Geraghty, *Immediate Past Chair, OPO Committee*
John C. Magee, MD, *OPTN President*

VOTING ITEM

1:40 – 2:00 p.m.

Normothermic Regional Perfusion (NRP) Workgroup

PJ Geraghty

Workgroup Chair; OPO Executive

John C. Magee

OPTN President; Transplant Surgeon

Rachel Beekman

Neurointensivist

Kris Croome

Abdominal Transplant Surgeon

David Foley

Abdominal Transplant Surgeon

Sarah Koohmaraie

Pediatric Transplant Coordinator

Lori Markham

OPO Executive

Kara Monday

Trauma Surgeon

Brendan Parent

Ethicist; Policy Researcher

Bill Ryan

OPTN Vice President of Patient and Donor Affairs; Family Member of a Deceased Donor

Lara Schaheen

Thoracic Surgeon

Bob Truog

Ethicist; Pediatric Anesthesiologist

Joseph Turek

Pediatric Cardiac Transplant Surgeon

Steve Weitzen

Heart Transplant Recipient

NRP Workgroup Objective and Charges

Objective

- Develop safeguards to ensure patient safety and improve family experience for donors undergoing NRP

Charges

- Propose OPTN policies, policy definitions, data collection, technical and quality standards, and standard practices that address patient safety for organ procurement organizations (OPOs) using NRP in patients from whom organs may be procured
- Propose OPTN data collection regarding the attempted and/or successful use of NRP in patients from whom organs may be procured

Development Timeline for Proposed NRP Policy

September 27, 2024

HRSA directed OPTN to **investigate specific incidents** involving potential violations of multiple OPTN policies

HRSA requested **additional information regarding relevant OPTN policies**

October 8, 2024

OPTN provided the requested information to HRSA

March 5, 2025

HRSA directed OPTN to **develop standards of practice** for the utilization of NRP to ensure patient safety

HRSA directed OPTN to **propose data collection protocols** for the monitoring of NRP

April 30, 2025

OPTN provided the requested information to HRSA

September 26, 2025

HRSA directed the OPTN Board of Directors to **establish an NRP workgroup** focused on patient safety and the experience of families of patients undergoing NRP

Development Timeline for Proposed NRP Policy (cont'd)



Policies to be Updated

Policy 2.2 OPO Responsibilities

- Clarify and reorder steps to better reflect the stages of the donation process

Policy 2.3 Required Disclosure Information for the Donor or Donor's Agent

- Include a reference to Policy 2.15.N.i Authorization for NRP

Policy 2.15 Requirements for Controlled Donation after Circulatory Death (DCD) Protocols

- Establish requirements governing the use of NRP as part of the controlled DCD process
- Proposed requirements would address, among other matters:
  - Authorization for NRP and specified surgical practices related to patient safety
  - Specified surgical practices related to patient safety
- Proposed requirements would also require OPOs to upload information related to NRP to OPTN data systems.

Policy 18.5 Reporting of Patient Safety Events

- Establish additional reporting requirements for specified patient safety events associated with NRP

Proposed NRP Policy Safeguards

- **Patient Safety**
  - Establish vascular safeguards intended to prevent cerebral reperfusion
  - Prohibit paralytic agents during NRP
  - Require an immediate response if cerebral perfusion, a physical response, or another sign of life is suspected
- **Authorization and Disclosure**
  - Establish consistent disclosures regarding NRP
  - Require disclosures to be communicated in understandable language and appropriately documented
- **Communication and Accountability**
  - Require team communication before NRP is initiated
  - Clarify roles and escalation processes
  - Establish documentation and patient-safety reporting requirements

NRP Implementation Plan

John C. Magee, MD, *OPTN President*

VOTING ITEM

Policy Pathways for Board Consideration

- **Routine Pathway**
  - Public comment and adjudication of comments precedes Board approval
  - Implementation follows Board approval
  - Timeline from public comment to Board approval is typically 6-12 months
- **Emergency Pathway (Policy E.7, OPTN Management and Membership Policies)**
  - Necessitated by a pending statutory or regulatory change, **an emergent public health issue or patient safety factors**, or a new medical device of technology that affects organ allocation
  - Emergency policy will expire within 12 months of the policy's effective date
  - Distributed for public comment within six months of approval, lasting at least 30 days
- **Proposed Approach**
  - Emergency adoption with phased implementation and public comment beginning November 13

Why Emergency Action is Proposed

- **November 2025:** OPTN and HRSA issued a safety notice addressing unintended brain reperfusion during NRP.
- **May 2026:** The OPTN President communicated updated recommendations that reinforced safeguards against brain reperfusion, prohibited paralytic agents that could mask signs of life, and clarified response and reporting expectations.
- **Continuing concerns:** Patient safety concerns have persisted, with increased MPSC investigations.
- **Risk of delay:** NRP will continue while additional safety requirements await implementation.

Recommendation to Approve as Emergency Action

Send out for public comment on November 13, 2026. Begin implementing urgent surgical safeguards in approximately 30 days (early December). Implement Phase 2 after the public comment period.

Proposed NRP Policy Phased Implementation Plan

November 6, 2026

Board vote

November 13, 2026

Release for public comment

~December 6, 2026

Implementation Phase 1 (approx. 30 days after vote): Surgical techniques; routine documentation; reporting requirements for patient safety events

December 28, 2026

Public comment period ends

Winter/Spring 2027

Implementation Phase 2 (3-6 months after public comment): Communication requirements; authorization requirements; documentation of plan return donor to the care of the hospital

Urgent Implementation – Phase 1 (~30 days post-vote)

Surgical techniques

- NRP must not begin until after 5 minutes have elapsed after pulselessness *and* the donor is pronounced dead by the hospital patient care team
- The NRP team must take all necessary steps to prevent blood flow to the brain (secure, transect, and vent blood vessels at risk of perfusing the brain)
- Paralytic agents must not be used in the context of NRP

Routine documentation

- For all actual/attempted recoveries using NRP, OPO must upload DCD flowsheet and operative note within 24 hours [requirement expands to include documentation of pre-withdrawal huddle when this is implemented]

Urgent Implementation – Phase 1 (~30 days post-vote), cont'd

Reporting requirements for patient safety events

- Reportable events: (1) Pre-mortem cannulation is performed and the patient's death does not occur within the expected time frame; (2) An unplanned pause is requested due to concern that perfusion may have been restored to the brain.
- Reportable events: There is withdrawal of life-sustaining support prior to the pre-recovery huddle

Phase 2 Implementation (Winter/Spring 2027)

Communication requirements

- **Pre-departure huddle:**
  - Includes OPO representative and lead surgeons from procurement and NRP teams
  - Participants review surgical approach and verify surgical team members who will be present
- **Prior to withdrawal of life sustaining therapy (WLST) huddle:**
  - Includes OPO staff, donor hospital operating room staff, surgical procurement team, and NRP team
  - Participants (1) review how to raise concerns, how to initiate an unplanned pause, surgical approach; and (2) confirm plan for how patient care will be transferred back to the hospital healthcare team if a concern is raised

Phase 2 Implementation (Winter/Spring 2027), cont'd

Authorization requirements

- Pre-mortem procedures (e.g., cannulation) require consent of the donor or donor's agent
- OPOs may have a separate authorization form for NRP or include NRP authorization in their standard authorization form for organ donation
- Disclosures regarding NRP must include the following information:
  - NRP is performed to increase the likelihood that the organs will be utilized for transplant
  - NRP restores perfusion to certain organs, and those organs are expected to resume function
  - There is a potential risk of restoring blood flow to the donor's brain; the team will make every effort to prevent this from happening

Phase 2 Implementation (Winter/Spring 2027)

Documentation of plan to return donor to the care of the hospital

- OPOs must have a documented plan for how patient care will be transferred back to the hospital healthcare team if concerns arise for cerebral perfusion or other physical responses during the NRP process

Next Steps: Tentative Timeline Recap

- Vote on Emergency Action: 11/6/26
  - Notice to community regarding Board emergency action and phased implementation timeline: 11/6/2026
- Public Comment Period (45 days): 11/13/26 – 12/28/26
- Items for **Phase 1**, urgent implementation go into effect: 12/6/26
- **Phase 2** of implementation will occur after public comment period (Winter/Spring 2027)

Discussion

Voting Recitals

- WHEREAS, on March 5, 2025, HRSA directed the OPTN to address patient safety for organ procurement organizations using normothermic regional perfusion (NRP), and on September 26, 2025, directed the Board to establish an NRP Workgroup to develop recommendations addressing patient safety and family experience in connection with the use of NRP;
- WHEREAS, the NRP Workgroup developed the proposed OPTN Normothermic Regional Perfusion Policy (the “NRP Policy”), which would amend OPTN Policies 2.2, 2.3, 2.15, and 18.5 to establish requirements for NRP authorization, surgical safeguards, pre-procurement communication, and patient safety event reporting;

Voting Recitals

- WHEREAS, the Board has determined the NRP Policy addresses an urgent patient safety need that warrants implementation as an emergency action, with concurrent distribution for public comment so the OPTN community may provide input without delaying these patient safety protections; and
- WHEREAS, the Board has reviewed the NRP Policy and believes that its approval as an emergency action is in the best interests of the OPTN.

Voting Resolution Language

- NOW THEREFORE, BE IT RESOLVED, that the Board hereby: (i) approves the NRP Policy, as developed by the NRP Workgroup, as an emergency action, to be implemented in phases beginning on December 6, 2026; and (ii) directs that the NRP Policy be distributed for public comment as soon as reasonably possible following the date of this resolution, and returned to the Board following the conclusion of the public comment period; and
- RESOLVED FURTHER, that the President and/or their designees are authorized to take all actions necessary to implement this resolution.