OPTN
Organ Procurement & Transplantation Network

Response to Questions from the Community

Thank you all for your detailed and thorough questions related to Normothermic Regional Perfusion (NRP). We appreciate and share your concern for patient and donor safety and consider it to be the top priority in the policy-making process.

History

At the direction of the Health Resources and Services Administration (HRSA), in October 2025, the OPTN convened an NRP Workgroup. The Workgroup's charge is to develop proposed policy elements related to NRP, informed by reported safety events, existing OPTN policy, ethical considerations, and current practice across the transplant system. This workgroup is in the early stages of policy development, and we look forward to continued feedback from the public as we move towards policy implementation.

In December 2025, the OPTN released a policy proposal addressing refinements to the pre-existing donation after circulatory death (DCD) policy for public comment. The DCD proposal aimed to improve safeguards for potential DCD patients and increase the information shared with potential donors and their families. The DCD Policy proposal was not intended to address all NRP-specific components, though it did include some direction regarding how NRP should be discussed with and explained to potential donors and their families.

During the public comment period for the proposed DCD Policy, commenters raised concerns related to NRP. These comments have been shared with the NRP Workgroup and they will endeavor to incorporate this public feedback into the policy development process to ensure that the concerns of the public, especially those related to patient safety, are appropriately addressed. Any policy proposal regarding NRP will proceed through the established steps for policy approval, including a public comment period and ultimately presentation to the OPTN Board for approval.

Circulation and Restoration of Function and the Definition of Death

One of the greatest safety concerns in the setting of NRP is the potential for reperfusion of the brain. Transecting and venting the vessels cephalad to the perfusion circuit should prevent this from occurring as there would be no pressure gradient to reperfuse the brain. Nonetheless, we must take every step to monitor for evidence of brain reperfusion (e.g. the return of respiratory drive).

The workgroup has concluded that paralytic agents must not be used for the purposes of NRP as they may obscure potential signs of life (e.g. any movement, including of respiratory muscles) that would indicate a failure in securing the cephalad vessels. There is broad consensus that the appearance of signs of life necessitates the discontinuation of NRP and the resumption of patient care by the primary care team.

Authorization vs. Consent

The NRP workgroup is developing guidelines to ensure that clear, plain language discussions of NRP are held with donor families and that all relevant information is communicated in a way that donor families

can understand. Families must have the opportunity to learn about the rationale for NRP, the likelihood of organ function resumption, and safeguards to prevent brain perfusion prior to making the decision to allow NRP.

Utility vs. Non-maleficence

As discussed in the OPTN white paper regarding the ethics of NRP, we believe that NRP represents a potentially significant tool for increasing the pool of usable donor organs. Equally importantly, NRP will provide the opportunity to more potential donors to realize their wish to be organ donors. The desire to help more recipients cannot come at the expense of safety for potential organ donors and therefore we are working to ensure that transplant providers have the necessary guidance and oversight to ensure that NRP does not cause harm to potential organ donors.

Surgical Risk and Minimum Requirements for NRP

While human error is always a possibility, the OPTN is developing policies to ensure that NRP can be conducted in a way that minimizes the risk of brain reperfusion to donors who have provided informed consent to the process. This work is motivated by HRSA's Critical Comment and the OPTN's desire to prioritize patient safety.

The Path to Policy

We acknowledge the need for continued research and reserve the right to amend OPTN policy as needed in the face of new information. Our goal is to bring experts in the field together with patients, family members, and other stakeholders in the transplantation system to synthesize the existing evidence and to develop policies and procedures that prioritize patient safety, transparency, and accountability.

As always, the OPTN welcomes public input on our policies and strives to address the needs of patients and the donation, procurement, and transplant community to the best of our abilities. We thank you for your comments and welcome future comments as we proceed towards implementation of new OPTN policy.