

**OPTN Ethics Committee  
Normothermic Regional Perfusion (NRP) Workgroup  
Meeting Summary  
July 14, 2022  
Conference Call**

**Keren Ladin, PhD, Chair**

## **Introduction**

The Normothermic Regional Perfusion (NRP) Workgroup met via Citrix GoToMeeting teleconference on 07/14/2022 to discuss the following agenda items:

1. Welcome and Introductions
2. Overview and Expectations
3. Background
4. Review of Ethical Principles
5. Timeline, Resources & Next Steps

The following is a summary of the Workgroup's discussions.

### **1. Welcome and Introductions**

The workgroup is comprised of a range of stakeholders and expertise. The members introduced themselves and their connection to transplant.

### **2. Overview and Expectations**

The Chair reviewed the charge of the OPTN Ethics Committee and outlined the parameters of the Committee's scope. This workgroup's project will culminate in a white paper, which is developed for informational purposes for the OPTN Board of Directors and is intended to guide OPTN operations and policy. The Chair outlined the workgroup member expectations for engagement and collaboration.

### **3. Background**

UNOS staff provided a brief background on the process, procedure, and growing practice of NRP. The definition of death, as determined by the Uniform Determination of Death Act (UDDA)<sup>1</sup>, and the dead donor<sup>2</sup> rule were both highlighted as additional context for this project.

### **4. Review of Ethical Principles**

The Chair reviewed the ethical principles of autonomy, non-maleficence, and utility that are under consideration in this project. The Chair highlighted how these principles are used in Ethics Committee

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<sup>1</sup> National Conference of Commissioners on Uniform State Laws, *Uniform Determination of Death Act*, Kauai: Hawaii, 1980.

<sup>2</sup> The dead donor rule "states that patients must be declared dead before the removal of any vital organs for transplantation." Robert D. Truog and Franklin G. Miller, "The Dead Donor Rule and Organ Transplantation," *The New England Journal of Medicine* (August 2008): 674-675. <https://doi.org/10.1056/NEJMp0804474>.

white papers and how they relate to NRP. Members were asked if there are additional ethical considerations the workgroup ought to deliberate on.

#### Summary of discussion:

A member suggested the inclusion of trustworthiness, fidelity, equity, and justice as principles for consideration. Trustworthiness and fidelity would be considered with regard to public trust, whereas justice and equity could consider who may, or may not, receive a transplant. A member suggested expanding the definition of autonomy in OPTN Ethics Committee work, and especially this project, to include relational autonomy.<sup>3</sup>

A member noted that some of the concerns that the transplant community has expressed about NRP are relevant to donation after circulatory death (DCD), which the community has largely accepted and endorsed. The member inquired if the workgroup needs to expand their consideration of NRP to include DCD. The member noted that by ligating the cerebral vessel brain death is imminent so the donor transitions from cardiac death to brain death. The member opined that in any case of cardiac death, it is possible that some level of brain activity could occur and noted that the procurement team clamps the aorta in DCD.

A member responded that in the example shared, circulatory death is declared and when the circulatory flow is restored there is an assumption that brain death proceeds but there is no confirmation that brain death has occurred or not. A member added that in Italy, procurement teams wait 20 minutes after circulatory death to ensure that brain death has proceeded before beginning procurement and noted that there may not be consensus from the community on DCD being ethical. The Chair clarified the scope of the project is limited to NRP but could consider the ethical principles for DCD and note what has been accepted for that practice if relevant. The Chair emphasized that the analysis of the white paper is restrained to the ethical considerations of NRP.

A member asked for clarification on the intersectionality of ethics and law, and the implications for the project. The Chair clarified that an ethical analysis informs what should, or should not be done, and why, while the legal analysis informs what is permissible by law. The workgroup will be considering these ethical principles within the scope of our current legal framework. The workgroup will consider what violates ethical principles or assumptions that are held, and if those violations are substantial enough to reconsider the practice of NRP. A member posited that a patient could support NRP in the context of efficiency and utilization, but further discussion regarding the ethical implications is needed to identify whether the practice is morally acceptable or not.

#### **5. Timeline, Resources, & Next Steps**

UNOS staff reviewed the project's timeline, which is slated for public comment in January 2023. Staff directed members to the resource library that exists on the Ethics Committee's Sharepoint site.

#### **Upcoming Meetings**

- August 4, 2022
- August 11, 2022

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<sup>3</sup> Carlos Gomez-Virseda, Yves de Maeseneer, and Chris Gastmans, "Relational autonomy: What does it mean and how is it used in end-of-life care? A systematic review of argument-based ethics literature," *BMC Medical Ethics* 20, 76 (Oct 2019). <https://doi.org/10.1186/s12910-019-0417-3>.

## Attendance

- **Workgroup Members**
  - Andrew Flescher
  - Bob Troug
  - Carrie Thiessen
  - Chris Brabant
  - Erin Halpin
  - Keren Ladin
  - Kevin Myer
  - Lainie Friedman Ross
  - Matt Hartwig
  - Nader Moazami
  - Rosa Guajardo
  - Sanjay Kulkarni
  - Sena Wilson-Sheehan
  - Sophoclis Alexopolus
- **HRSA Representatives**
  - Edna Dumas
  - Jim Bowman
- **SRTR Staff**
  - Bryn Thompson
- **UNOS Staff**
  - Brian Shepard
  - Christine Chyu
  - Cole Fox
  - Eric Messick
  - Keighly Bradbrook
  - Kim Uccellini
  - Krissy Laurie
  - Kristina Hogan
  - Matt Belton
  - Matt Cafarella
  - Roger Brown
  - Stryker-Ann Vosteen
  - Tina Rhoades
- **Other Attendees**
  - Kristine Browning