OPTN Ethics Committee Normothermic Regional Perfusion (NRP) Workgroup Meeting Summary December 8, 2022 Conference Call

Keren Ladin, PhD, Chair

Introduction

The Normothermic Regional Perfusion (NRP) Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 12/8/2022 to discuss the following agenda items:

- 1. Intensivist Perspective
- 2. Summary of NRP Poll Feedback
- 3. Outline of White Paper
- 4. Next Steps

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

1. Intensivist Perspective

Dr. Harry Peled presented to the workgroup and provided the perspective of an intensivist, which is a physician who provides specialized care for critically ill patients.

Summary of discussion:

The Workgroup reviewed how variation in protocols and limited number of intensivists exacerbates challenges in defining appropriate NRP protocols. Members noted specific challenges associated with communication between Organ Procurement Organizations (OPOs) and transplant hospitals on NRP protocols, where in the body vessels are ligated and what that means for circulation, brain flow monitoring, and clarity in the definition of death.

A representative from HRSA recommended searching for any small or large animal studies that have been conducted to advise on some of the group's concerns on the potential of blood flow due to reperfusion. Another member recommended looking into focus groups for donor families to have a better understanding of what type of information they want to know as part of the donation process.

2. Summary of NRP Poll Feedback

The Workgroup reviewed the feedback from a poll that members completed. The poll asked if members changed their mind on NRP through the progression of the workgroup, if members needed more information or data to inform their position, and what members' stances are on NRP. A large majority of the workgroup members participated in the poll, about 84%. The poll showed most members have changed their minds in the course of the NRP Workgroup discussions, and there were concerns about whether NRP could be appropriately and ethically pursued in the current environment.

Summary of discussion:

A member inquired if there is going to be a discussion about what information is needed for NRP to be permissible. The Chair noted that those discussion have been ongoing and the white paper will reflect

the discussions and decisions the workgroup has come to. A member noted that there are points of consensus on some topics, such as uncontrolled NRP.

3. Outline of White Paper

The Workgroup reviewed the outline of the white paper and timeline for completion. The majority of the writing will occur from OPTN Ethics Committee members on the workgroup since Ethics is the sponsoring committee for this project. There is some potential for variability in the timeline as the Workgroup prepares for a special public comment cycle.

Next steps:

Staff will reach out to Committee members with writing assignments.

Upcoming Meetings

- January 26, 2023
- February 9, 2023
- March 9, 2023

Attendance

• Committee Members

- o Amy Friedman
- o Andy Flescher
- o Bob Truog
- o Carrie Thiessen
- o Erin Halpin
- o Jonathan Fisher
- o Julie Spear
- o Keren Ladin
- o Kevin Myer
- o Lainie Ross
- o Nader Moazami
- o Rosa Guarjardo
- o Sanjay Kulkarni
- o Sena Wilson-Sheehan
- o Sophoclis Alexopolous

• SRTR Representatives

- o Bryn Thompson
- **HRSA Representatives**
 - o Edna Dumas
 - o Jim Bowman
 - o Marilyn Levi
- UNOS Staff

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- o Cole Fox
- o Houlder Hudgins
- o Kristina Hogan
- o Kim Uccellini
- o Laura Schmitt
- o Michelle Rabold
- Other Attendees
 - o Harry Peled