

Meeting Summary

OPTN Ethics Committee
Normothermic Regional Perfusion (NRP) Workgroup
Meeting Summary
October 27, 2022
Conference Call

Keren Ladin, PhD, Chair Andrew Flescher, PhD, Vice Chair

Introduction

The Normothermic Regional Perfusion (NRP) Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 10/27/2022 to discuss the following agenda items:

- 1. Welcome and Agenda Review
- 2. Review of POC and Ethics Committee Feedback
- 3. Review Updated Outline: Workgroup Discussion
- 4. Closing Remarks

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

1. Welcome and Agenda Review

The Chair prefaced the meeting with an overview of the agenda for the meeting, and welcomed several observers on the call, reminding all of meeting expectations and decorum.

2. Review of POC and Ethics Committee Feedback

The Vice-Chair shared the feedback from the Policy Oversight Committee (POC). The main questions related to the timeline of the project, whether additional evidence gathering was necessary and appropriate, and a request for the Ethics Committee to update the POC next month with the decision of whether the white paper would proceed for January 2023 public comment. The Ethics Committee voted to postpone the white paper and not proceed with January 2023 public comment. The Committee raised questions concerning public trust and what the image of NRP might be from an outsider's perspective. Ethics Committee members agreed with ethical concerns brought up concerning thoracoabdominal NRP (TA-NRP) and abdominal NRP (A-NRP), and TA-NRP exhibited an increased potential of reperfusion to the brain.

Summary of discussion:

Members discussed a variety of concerns, attempting to gain further clarity on use of terminology such as resuscitation, reperfusion, and reoxygenation of blood. Some members raised the question of how the discussion relating to NRP might affect the discussion surrounding donation after cardiac death (DCD). The Chair reminded the Workgroup that DCD is not within scope of their discussion, to which members agreed. A member emphasized the importance of what takes place just before any procurement: the appropriate management of care of the patient. Other members agreed that this is critical to any organ procurement, however, not all procurements involve the same level of biological intricacy as NRP. For many members of the Workgroup, NRP raises concerns of blood flow to the brain, as it is unknown to what extent there is any incidental flow, if at all. Adjacent to the concern of blood flow was the ensuring the do no harm principle, members were apprehensive to say whether pain can

be felt or not, and what ethical implications could exist in light of that question. Members could not comfortably agree on whether it is the reversal of cessation of circulatory function or the potential for blood flow to the brain that gives them reason to pause as they progress in their discussion. In light of these remaining questions, the Chair advocated for the paper to be transparent about how little is still know about NRP and what happens in the body after withdrawal of life-sustaining measures.

3. Review Updated Outline

Staff presented the updated outline to the workgroup, citing changes that occurred due to the conversation during the Ethics Committee in-person meeting, and the discussion that was held today. The ethical principles of do no harm, respect for persons, and utility remain the primary pillars of the paper.

4. Closing Remarks

Staff will be sending out a survey to all members of the workgroup, to ascertain their current feelings and sentiments regarding NRP and the discussions held thus far. The goal is to also bring to light any further unresolved questions members might have, and if their perspective has potentially changed over the course of these meetings. The subgroups will resume meeting as well with the updated outline, with some revisions to participants on subgroups that reflect the changes to the outline.

Upcoming Meetings

- November 10, 2022
- December 8, 2022

Attendance

• Committee Members

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

• HRSA Representatives

o Jim Bowman

UNOS Staff

- o Cole Fox
- o Kristina Hogan
- o James Alcorn
- o Kim Uccellini
- o Laura Schmitt
- o Rebecca Murdock
- o Stryker-Ann Vosteen

• Other Attendees

- o Bilal Mahmood
- o Igor Gosev
- o Katie Dokus
- o Leway Chen
- o Marcia Sheegog
- o Robert Gruenenfeder