

**OPTN Executive Committee  
Meeting Summary  
September 26, 2024  
Webex**

**Richard Formica, MD, Chair**

## **Introduction**

The OPTN Executive Committee met via Webex teleconference on 09/26/2024 to discuss the following agenda item:

1. Welcome & Announcements
2. HIV Organ Policy Equity (HOPE) Act Comment\*
3. New Projects from the Policy Oversight Committee (POC)\*
4. NRP Project Directive\*

The following is a summary of the Committee's discussion.

### **1. Welcome & Announcements**

Richard Formica, Chair of the Executive Committee, welcomed the committee to their meeting and presented the agenda.

### **2. HIV Organ Policy Equity (HOPE) Act Comment\***

Stephanie Pouch, Chair of the Disease Transmission and Advisory Committee (DTAC) presented the draft comment from the OPTN on the HIV Organ Policy Equity (HOPE) Act proposed rule. Dr. Pouch presented the background on the HOPE Act and the existing protocols regarding the transplantation of HIV positive organs. Dr. Pouch presented the history of the OPTN's comments in response to the HOPE Act and presented information on how the new proposed rule could impact the OPTN. Dr. Pouch shared that the proposed rule removes the National Institutes of Health (NIH) Clinical Research and Institutional Review Board (IRB) requirements for kidney and liver HOPE Act organ transplants and directs the OPTN to amend policies and standards of quality for kidney and liver HOPE Act transplants. Dr. Pouch noted that these actions to be completed within 15 months from when final rule is published.

Dr. Pouch then shared the key points in the OPTN's comment in response to the rule. She shared that the OPTN's comment:

1. Affirms support for removing clinical research IRB requirements for kidney and liver HOPE Act organ transplants.
2. Notes that revising clinical research criteria for other organs may help remove current barriers that inhibit participation in HOPE Act.
3. States that feasibility of 15-month timeline for implementing standards of quality depends on specific language of finalized rule and whether new data collection will be required.

### Summary of Discussion:

Multiple committee members voiced their support of the draft OPTN comment on the proposed rule. The committee discussed the potential level of effort that would be needed if the OPTN were to collect

additional data on HIV positive organs. The committee discussed how this proposed rule could increase opportunities for transplants for some populations.

The committee discussed why the proposed rule only addressed kidneys and livers and why the removal of NIH and IRB requirements would not be applied to all abdominal organs. Dr. Pouch reminded the committee that in 2021 the OPTN recommended removing the requirements for all abdominal organs but currently, the proposed rule only includes kidneys and livers.

Vote:

The committee unanimously approved the submission to the Federal Register, the OPTN response to the HHS proposed rule “Organ Procurement and Transplantation: Implementation of the HIV Organ Policy Equity (HOPE) Act”, as set forth in the materials distributed on September 20, 2024, pending any non-substantive edits subject to the OPTN President’s review and approval.

Next Steps:

The comment will be submitted to the Federal Register on behalf of the OPTN.

**3. New Projects from the Policy Oversight Committee (POC)\***

Jennifer Prinz, Chair of the Policy Oversight Committee (POC) presented three new projects and one modified project. Ms. Prinz reviewed the parameters by which the POC reviews new project proposals and the projected resource estimates for the four projects.

Ms. Prinz presented a new project from the Lung Transplantation Committee to Modify Lung Donor Testing Data Collection and shared that the purpose of the project is to promote efficiency of lung allocation by considering changes to the OPTN data collection. Ms. Prinz shared additional information on the new data that would be collected and the existing data fields that would be updated. For each project, Ms. Prinz shared the expected resource estimate, benefit score, strategic goal alignment, key metrics, public comment date, and shared the POC’s discussion points and recommendation.

Ms. Prinz presented a white paper from the Ethics Committee on the Ethical Analysis of Possible Impacts of Xenotransplantation on Human Allograft Organ Allocation. Ms. Prinz shared that the white paper was developed based on a recommendation from OPTN leadership to explore the ethical considerations of how xenotransplantation may interact with the human allograft allocation system. Ms. Prinz noted that it is important to consider these potential interactions through an ethical lens before these questions need to be considered in real-time. Ms. Prinz highlighted that the Health Resources and Services Administration (HRSA) indicated the OPTN has authority to address the questions outlined in the paper, however the paper may not analyze issues of xenotransplantation that fall outside the scope of the OPTN.

Ms. Prinz presented a project update from the Multi-Organ Transplantation (MOT) Committee to Establish Comprehensive Multi-Organ Allocation Policy. Ms. Prinz shared that the initial project was approved in October 2022 and focused on kidney-MOT allocation, however, this updated project has been modified to include MOT allocation generally, not only kidney-MOT allocation. Ms. Prinz shared that the POC was re-sharing the project with the Executive Committee due to the change in the project’s projected resource estimates, and to provide an update on the project’s efforts to date. Ms. Prinz shared the public sentiment the project received when it was initially out for public comment and the project’s work plan.

Ms. Prinz presented a new project from the Organ Procurement Organization (OPO) Committee on Machine Perfusion Data Collection to collect more granular data on the use of machine perfusion and normothermic regional perfusion (NRP). Ms. Prinz shared that the OPO Committee noted that improved

data collection will help the community better understand the impact on organ allocation and placement as well as patient outcomes.

Summary of Discussion:

A committee member asked if the calculations for resource estimates would need to be recalculated once more contractors are involved with OPTN work. Ms. Prinz shared that the information shared during the meeting is based on the OPTN's current state.

When discussing the new project from the Ethics Committee, a committee member noted that although the ethical considerations of xenotransplantation are important to consider, they encouraged the OPTN to also consider developing policy around the practice.

When discussing the new project from the OPO Committee, a committee member asked about the project's benefit score and how the POC assigned the project a medium benefit score. Representatives from HRSA commented on the need for OMB approval on the data collection associated with the project, and it was shared that OMB approval was already considered in the project's anticipated timeline. The committee discussed modifying the project's timeline to have the project have an earlier Board approval date than the currently projected date of December 2025.

Vote:

The Executive Committee approved the initiation and continuation of the following projects from the Policy Oversight Committee (POC):

- Modify Lung Donor Testing Data Collection (Lung Transplantation Committee)
- Ethical Analysis of Possible Impacts of Xenotransplantation on Human Allograft Organ Allocation (Ethics Committee)
- Establish Comprehensive Multi-Organ Allocation Policy (Multi-Organ Transplantation (MOT) Committee)
- Machine Perfusion Data Collection (Organ Procurement Organization (OPO) Committee)

**4. NRP Project Directive\***

Richard Formica, OPTN President, presented a project directive on practices surrounding normothermic regional perfusion (NRP). Dr. Formica shared that NRP is currently governed by DCD policy and stated that there is a need for the OPTN to develop requirements for the standardized practice of NRP. Dr. Formica reminded the committee of the OPTN's prior efforts related to NRP, specifically referencing the Ethics Committee White Paper on NRP. He shared that in the white paper, the Ethics Committee suggested that the OPTN develop standardized processes for NRP. Dr. Formica suggested that the Executive Committee could direct the Operations and Safety Committee (OSC) to establish requirements for standardized practices in the use of NRP.

Summary of Discussion:

Committee members supported the directive and agreed that the OPTN should develop standardized practices and guidelines for NRP.

Vote:

The committee unanimously approved the following resolution:

The OPTN Operations and Safety Committee is charged with establishing requirements for standardized practice in the use of NRP in organ procurement. The committee will share a progress report with the Board of Directors no later than November 15, 2024.

The meeting adjourned.

**Upcoming Meetings:**

- October 24, 2024
- November 14, 2024
- December 12, 2024

## Attendance

- **Committee Members**
  - Andrea Tietjen
  - Emily Blumberg
  - George Surratt
  - Jen Lau
  - Jennifer Muriett
  - Lloyd Ratner
  - Luis Hidalgo
  - Macey Levan
  - Richard Formica
- **HRSA Representatives**
  - Adrienne Goodrich-Doctor
  - Frank Holloman
- **UNOS Staff**
  - Janis Rosenberg
  - Kaitlin Swanner
  - Lauren Mauk
  - Lindsay Larkin
  - Maureen McBride
  - Michael Ghaffari
  - Morgan Jupe
  - Robert Hunter
  - Roger Brown
  - Susan Tlusty
  - Susie Sprinson
  - Viktoria Filatova
- **Other Attendees**
  - Andrew Flescher
  - Jennifer Prinz
  - PJ Geraghty
  - Stephanie Pouch