

**OPTN Executive Committee  
Meeting Summary  
December 12, 2024  
Webex**

**Richard Formica, MD, Chair**

## **Introduction**

The OPTN Executive Committee met via Webex teleconference on 12/12/2024 to discuss the following agenda item:

1. Welcome & Announcements
2. Draft OPTN Response to 60-day Federal Register Notice (FRN) for Process Data for Organ Procurement and Transplantation Network (OMB No. 0906-xxxx—New) \*
3. New Project from the Policy Oversight Committee (POC) \*
4. Operations & Safety Committee Normothermic Regional Perfusion Report-Out to the Board

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

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

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

### **2. Draft OPTN Response to 60-day Federal Register Notice (FRN) for Process Data for Organ Procurement and Transplantation Network (OMB No. 0906-xxxx—New) \***

Jesse Schold, Chair of Data Advisory Committee (DAC), presented an overview of the OPTN's drafted response for new data collection forms proposed in a Federal Register Notice (FRN). Dr. Schold voiced that the FRN proposal would impact the pre-waitlist referral form, pre-waitlist evaluation form, and ventilated patient form. Dr. Schold communicated the timeline of the FRN and presented a summary of the OPTN's drafted response. Dr. Schold shared that the OPTN supports the stated goals for the new data collection, spoke about feedback from the DAC on the FRN, and revealed general themes in the draft response. Dr. Schold presented feedback from the DAC on each data collection form, and shared other feedback received on the forms that did not align with just one of the three noted forms.

#### Summary of Discussion:

The committee discussed the draft response from the OPTN and determined there were many recommendations in the response that are likely outside the scope of the federal register notice. The committee discussed implementing the practices noted in the forms and whether this would be within the purview of the OPTN or whether HRSA would implement these changes directly. The committee voiced their approval for HRSA to implement the changes decided upon when the time comes.

A committee member commented that the success of the notice and the forms is dependent on the collaboration between electronic medical record systems, transplant hospitals, and OPOs when it comes to implementation. The committee discussed the efforts of multiple OPTN Working Groups that collaborated on drafting the OPTN's response on the notice.

Vote:

The committee unanimously approved the following resolution:

RESOLVED, that the OPTN Response to the Federal Register 60-day Notice *Process data for Organ Procurement and Transplantation Network (OMB No. 0906-xxx – New)* as set forth in the materials distributed to the Executive Committee on December 10, 2024, is hereby approved.

Next Steps:

The OPTN's official response to the federal register notice will be submitted by contractor staff on behalf of the OPTN.

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

Erika Lease, Vice Chair of the Policy Oversight Committee (POC) presented a new project to Require West Nile Virus Seasonal Testing for Donors from the Disease Transmission Advisory Committee (DTAC). Dr. Lease communicated the Executive Committee's charge when reviewing new projects from the POC, the purpose of the project, resource estimates associated with the project, the project score, strategic plan alignment, key metrics, and the expected public comment period. Dr. Lease outlined the POC's discussion and recommendations for the project and confirmed that the POC unanimously recommended approval of the new project.

Summary of Discussion:

The committee discussed West Nile Virus and the rate at which it is found in transplant patients. A committee member commented that it is important that the testing is performed and returned to the OPOs and transplant centers before transplantation as West Nile Virus is fatal if contracted.

A committee member commented that the Executive Committee must strive to continue to understand the benefit score the POC assigns to new projects and how the POC prioritizes new projects. Dr. Lease agreed that it is important to understand the priorities of the OPTN when assigning a benefit score and that this would be something to consider when there is less change happening around the OPTN.

Vote:

The Executive Committee approved the initiation of the following project from the Policy Oversight Committee (POC):

Require West Nile Virus Seasonal Testing for Donors (Disease Transmission Advisory Committee)

**4. Operations & Safety Committee Normothermic Regional Perfusion Report-Out to the Board**

Steve Potter, Vice Chair of the Operations and Safety Committee (OSC) provided an update to the Board on the committee's efforts in normothermic regional perfusion (NRP) practices. Dr. Potter shared that on September 26th, the Executive Committee directed the OSC to establish requirements for standardized practice in the use of NRP in organ procurement. Dr. Potter presented a summary of the OSC's conversation on the subject and communicated that the Board received a written report from the committee in their December Board meeting materials. The committee discussed exploring policy, guidance documents, or data collection projects for NRP, and Dr. Potter voiced the considerations for each potential project type.

Dr. Potter conveyed that the OSC is expected to submit a request for feedback on NRP during the Winter 2025 Public Comment Cycle to solicit feedback on the recommended solutions to inform future guidance, policy, and/or data collection efforts.

### Summary of Discussion:

The committee discussed when the OSC should submit a formal project proposal and not just a request for feedback for OPTN public comment. A representative from HRSA suggested that the OPTN submit the project as an emergency action to make the practices surrounding NRP a requirement and not just guidance. Dr. Formica said that it is important for the OPTN follow the policymaking process on the subject in an expeditious manner but did not agree emergency action was the appropriate solution.

A committee member asked whether there was language in the OSC's report from an organ procurement organization's (OPO's) perspective on the practice of NRP. Dr. Potter detailed what was included in the report and asked for the OPO representatives' feedback on the information.

The committee continued to discuss the different options to consider for sharing the NRP project and practices with the OPTN community. Dr. Potter revealed that the OSC believed submitting a request for feedback for Winter 2025 Public Comment was the most logical next step, as the committee could then receive feedback from the community and make a holistic policy proposal. Some committee members worried that submitting the project for a request for feedback may lead to broad feedback that may not be relevant to the project or the purview of the OPTN.

### Next Steps:

Dr. Formica instructed the OSC to develop a guidance document on the practices of NRP to submit for a special public comment period in early 2025.

### **Upcoming Meetings:**

- January 16, 2025

## Attendance

- **Committee Members**
  - Andrea Tietjen
  - Dianne LaPointe Rudow
  - Emily Blumberg
  - Erika Demars
  - George Surratt
  - Jen Lau
  - Jennifer Muriett
  - Macey Levan
  - Richard Formica
  - Silas Norman
- **HRSA Representatives**
  - Christopher McLaughlin
  - Jayme Locke
  - Marilyn Levi
  - Ray Lynch
  - Stephanie Grosser
- **UNOS Staff**
  - Cole Fox
  - Joann White
  - Krissy Laurie
  - Liz Robbins Callahan
  - Maureen McBride
  - Morgan Jupe
  - Nadine Rogers
  - Rebecca Murdock
  - Roger Brown
  - Susie Sprinson
- **Other Attendees**
  - Christine Jones
  - Erika Lease
  - Jesse Schold
  - Kimberly Koontz
  - Lisa McElory
  - Mary Lavelle
  - Rachel Shapiro
  - Rick Hasz
  - Steven Potter
  - Sumit Mohan
  - Tennille Daniels