

# OPTN Board of Directors Meeting Summary

## Meeting Information: Agenda and Attendees

Thursday, April 17, 2025 | 1:00–3:00 p.m. ET Location of Event: Zoom

The following are meeting minutes from the OPTN Board of Directors meeting, which took place on **April 17, 2025, 1:00–3:00 p.m. ET.**

### Agenda

#### Open Session

- Welcome and Announcements
- Patient Representation on the OPTN Board
- Updates on HRSA Directives
  - Allocating Organs Out of Sequence (AOOS)
  - Normothermic Regional Perfusion (NRP)
  - Donor Derived Transmission Event
- Policy Project Update
  - Develop Lung Review Board Educational Narrative Examples (Lung Transplantation Committee)
  - 2025 Histocompatibility Human Leukocyte Antigen (HLA) Table Update (Histocompatibility Committee)
- OPTN Strategic Plan Report Out
- Pediatric HIV Organ Policy Equity (HOPE) Act Patient Variance

#### Closed Session

- The Board met in a closed session.

### Attendees

Attendee Name(s)	Affiliation
Richard Formica, Lloyd Ratner, Jenn Muriett, Andrea Tietjen, Andrew Kao, Allyson Hart, Catherine Kling, Christopher M. Jones, Colleen McCarthy, Deborah Adey, Deborah Levine, Denise Abbey, Dev Desai, Dianne LaPointe Rudow, Dorrie Dils, Caroline Alquist, Emily Blumberg, Erika Demars, Gaurav Gupta, George Surratt, Glen Kelley, J. David Vega, Jon Snyder, Kenneth McCurry, Kristen Welker-Hood, Jennifer Reese, Laura Butler, Luis Hidalgo, Martha Pavlakis, Michael Kwan, Nancy Metzler, Robert Harland, Sara Rasmussen, Silas Norman	OPTN Board of Directors

Attendee Name(s)	Affiliation
Aite Aigbe, Arjun Naik, Jim Bowman, Jon Mills, Mesmin Germain, Patrick Mauro, Raymond Lynch, Shantel Delgado, Steve Keenan, Marilyn Levi	HRSA Representatives
Christine Jones, Andrew London, Anthony LaBarrie, Becca Fritz, Christine Sledge, Eli Greenspan, Emily Elstad, George Barnette, Jadyn Dunning, James Montgomery, Karen Edwards, Lori Downing, Tennille Daniels, Tessa Kieffer, Thomas Barker	OPTN Board Support Staff
Cole Fox, Emy Trende, Lauren Mauk, Liz Robbins Callahan, Keighly Bradbrook	OPTN Operations Contractor Staff
Rexanah Wyse Morrisette	OPTN Interim Executive Director
Roslyn Mannon, Ryutaro Hirose	SRTR Representatives

## Meeting Summary

### Welcome and Announcements

The Board President welcomed attendees and began the meeting.

### Patient Representation on the OPTN Board

The Chair of the Nominating Committee provided an update on the process to fill the seats of the eight out of eleven patient representatives who resigned from the Board. The Final Rule (§ 121.3(a)(1)) requires that “[a]t least 25 percent” of Board members must be comprised of patient representatives. The three patient representatives remaining on the Board joined the Nominating Committee to provide valuable insight into the search for patient and donor representative candidates to fill the empty slots. The Committee is looking for candidates who are patients, donors, or family members of a deceased donor and have prior Board experience, as well as knowledge of how the OPTN system operates and how policy is developed. The new patient Board members will serve a short term (i.e., April through 6/30, when the newly elected Board is seated). The Committee identified 13 qualified candidates. Committee members selected their top eight candidates and classified the remaining candidates as alternates. The Committee began outreach to the top eight candidates on 4/15. The Committee will continue to conduct outreach to the Patient and Donor Affairs and the Patient Affairs Committees to identify additional candidates/alternates.

The Board discussed whether decisions that would be made by the Board would be legal until the Board is able to fill the eight empty seats. It was determined that lack of adequate patient representation resulting in failure to achieve voting quorum or meet Final Rule requirements (that 25% of Board members must be comprised of patient representatives) will not affect the turnover to the new Board at the end of June. However, the Board cannot take any voting action until they can achieve quorum and meet Final Rule requirements. The legal team associated with the Board Support Contractor is currently looking into whether the Board has any authority to make decisions under Delaware state law despite not meeting the federal Final Rule requirements. The Board President emphasized the importance of ensuring that the approach to filling the patient representative seats fully aligns with legal process.

requirements. The Nominating Committee will keep the Board informed of all status updates on filling the eight patient representative seats.

***Updates on HRSA Directives: Allocating Organs Out of Sequence (AOOS), Normothermic Regional Perfusion (NRP), Donor Derived Transmission Events***

The Board President provided an update on the response to HRSA Directives on Allocating Organs Out of Sequence (AOOS), Normothermic Regional Perfusion (NRP), and Donor Derived Transmission Events.

***HRSA Directive on Allocating Organs Out of Sequence (AOOS)***

As requested, on **March 31, 2025** the OPTN submitted a workplan to HRSA to complete the following actions:

- Provide a detailed remediation plan to improve OPTN allocation policy requirements and policy definitions.
- Propose a detailed, prospective OPTN compliance plan to ensure OPTN members come into compliance with the regulatory wastage provision and otherwise comply with statutory and regulatory requirements for the allocation of organs.
- Create transparency into the submission, approval, and performance of protocols under the OPTN expedited placement variance<sup>11</sup> to ensure government oversight, increase patient awareness and public transparency of variances, and increase patient access to transplants.
- Propose a tool to provide public transparency into how frequently patients are excluded from access to organs for which they have been matched as a consequence of AOOS.

OPTN working groups are addressing the different components of the directives in the U.S. Department of Health and Human Services (HHS) Secretarial letter on the AOOS response.

***HRSA Directive on Normothermic Regional Perfusion (NRP)***

The letter regarding the NRP directive directs the OPTN to complete the following actions by **April 30, 2025**:

- Propose OPTN policies, policy definitions, data collection, technical and quality standards, and standard practices that address patient safety for organ procurement organizations using NRP in patients from whom organs may be procured
- Propose OPTN data collection requirements regarding the attempted and/or successful use of NRP in patients from whom organs may be procured

***HRSA Directive on Donor Derived Transmission Events***

The following actions were completed by **April 15, 2025**:

- Obtained from six OPOs 12 months of data related to screening protocols for donors with risk factors for rabies and the outcomes of testing on those donors.
- Drafted an interim communication to be sent to the OPTN membership jointly by HRSA, the OPTN, and OPTN Disease Transmission Advisory Committee (DTAC) chair to remind members of current

guidance regarding screening for donor-derived infection. This draft was communicated to HRSA via email by the due date.

The following actions are due to be completed by **July 2, 2025**:

- Using data gathered by the OPTN contractor, convene the OPTN DTAC to propose improvements to OPTN policy that reduce risk of donor derived rabies.
- Describe in writing how to integrate patient and provider perspectives, concerns, and education into any proposed policy changes as well as any potential recommendations for the use of post-exposure prophylaxis

The standard Organ Procurement Organization (OPO) questionnaire asks if the exposure was due to a bite or a scratch. The questionnaire also asks whether the animal was a wild animal or a domesticated/household animal. Wild animal exposures are less common; however, wild animal exposures are much more likely to result in disease transmission.

### ***Policy Project Update***

The Board President provided an update on policy projects that were advanced at the April 3, 2025 Executive Committee meeting.

### ***2025 Histocompatibility HLA Table Update (Histocompatibility Committee)***

Following a presentation by the Policy Oversight Committee (POC), the Executive Committee approved this project.

### ***Develop Lung Review Board Educational Narrative Examples (Lung Transplantation Committee)***

The Lung Transplantation Committee proposed developing clinical case narratives with consistent content to help regional review boards and committees become more standardized in their approach to making decisions for lung transplant exceptions. Following a presentation by the POC, the Executive Committee approved this project.

### ***OPTN Strategic Plan Report Out***

The OPTN Interim Executive Director provided an update on the progress toward the goals and objectives outlined in the OPTN Strategic Plan since the last review in November 2024. The Board received a 19-page Strategic Plan report in advance of the meeting. The OPTN Strategic Plan focuses on four key goals: (1) Increasing opportunities for transplants, (2) Optimizing organ use, (3) Enhancing OPTN efficiency, and (4) Supporting OPTN Modernization initiatives. The OPTN has been diligently working on objectives within the four key goals.

### ***Increase Opportunities for Transplants***

The first OPTN Strategic Plan goal is to *improve offer acceptance for deceased donation and enhance access to living donation to increase patients' opportunities for transplant.*

The key metrics for this goal include offer acceptance rates, time to acceptance, declines, and living donor transplants. Overall acceptance rates have remained relatively stable. Notably, however, lung acceptance rates have shown a downward trend since quarter one of 2022. The OPTN has begun investigative work to better understand the cause of this decline. There has been an increase in the time

from the first to the last electronic offer for most organs, with the exception of the liver, which has leveled out and the lung, which has begun to decrease since Quarter Three of 2022. Increasing time between offers can lead to organ viability issues; therefore, this metric should be monitored closely.

The median number of declines prior to the first organ offer acceptance remains stable for the heart and liver. The median number of declines for kidneys saw a small increase after Quarter One of 2021 but has since stabilized. Lastly, the lungs have experienced an increase in declines since Quarter Three of 2022 but have since stabilized. The Strategic Plan report notes that there has been a steady increase in living donor kidney transplants. This increase reflects the OPTN's efforts to promote living organ donations. The Interim Executive Director shared that the OPTN should consider maximizing opportunities presented by National Donate Life Month (April) with stakeholders to encourage more people to sign up to be an organ donor.

### ***Optimizing Organ Use***

The second OPTN Strategic Plan goal is *optimizing organ use for transplantation, while improving equity to benefit all patients*.

The OPTN continues to closely monitor heart and lung non-utilization rates and is working to identify and address barriers to utilization. The higher kidney donor profile index (KDPI) kidneys are still being utilized at a lower rate. The OPTN must continue to look for ways to utilize these organs.

The OPTN is working to understand the factors contributing to the variations of liver non-usage by donor age and Donation after Circulatory Death (DCD) status. The OPTN is also continuing to monitor the effects of policy changes to the Access to Transplant Scores (ATS) and is seeing progress toward the OPTN and equity goals. The Interim Executive Director noted that the Minority Affairs Committee is working on removing race from KDPI, which could be an opportunity to look into what other factors may need to be changed or removed.

### ***Enhancing OPTN Efficiency***

The third OPTN Strategic Plan goal is to *increase the efficiency of the OPTN through improvement and innovation to serve the greatest number of patients*.

The OPTN is making progress on reducing the time for policy development; however, this continues to be an iterative process. For the first time in OPTN history, the OPTN is ensuring that policy projects are aligned with the strategic goals and have robust policy project benefit scores. In December 2024, the POC discussed potential adjustments to the existing benefit score framework. The Vice Chair of the POC emphasized the importance of considering the risk of not doing a project as well as the risk of pursuing the project. The Interim Executive Director reported that the Chair of the POC suggested quantifying risk levels (e.g., no risk, mild risk, or severe risk) to weigh risks effectively in scoring decisions. A POC member raised concerns about the binary nature of scoring and suggested introducing a middle tier for partial alignment with less weight than full alignment. There have not been any resolutions yet, but these topics are part of ongoing discussions. The Board President shared that the POC has collaborated with the Executive Committee to identify policy proposals that should be prioritized based on their alignment to the Strategic Plan and cost.

### ***Supporting OPTN Modernization Initiatives***

The fourth OPTN Strategic Plan goal is to *collaborate to lay the foundation for the OPTN of the future*.

HRSA is continuing to move forward with the multi-vendor OPTN contractor model. The OPTN is monitoring these changes from a singular to a multivendor space; however, more information is needed from the oversight authority (i.e., HRSA) to be able to better track progress.

A Board member asked if the pediatric population is being kept in mind as the OPTN Modernization Initiative moves forward, considering that they are often not best served by efficiency. In response, the Interim Executive Director emphasized the importance of ensuring that all of the populations impacted by this modernization process are taken into consideration.

The OPTN will continue to monitor progress of Strategic Plan goals against metrics and adjust as needed.

### ***Pediatric HIV Organ Policy Equity (HOPE) Act Patient Variance***

The Board President provided an update on the HOPE Act patient variance.

The OPTN was approached by University of California, San Francisco (UCSF) regarding an HIV-positive pediatric patient in need of an organ offer. UCSF has been at the forefront of HIV-positive transplants and Institutional Review Board (IRB) protocols. The Board President shared that it was challenging to find a match for the patient due to sensitization and them being on a time-limited visa. Also, pediatric patients are not currently included under IRB approval for the HOPE Act. This presented an additional challenge, in addition to the challenge that the OPTN has not yet moved the HOPE Act for abdominal organs into routine clinical practice. Although it is medically appropriate to transplant an HIV organ into the patient, UNet does not recognize them as eligible for an HIV-positive organ. Board Leadership discussed a potential mechanism to be able to offer HIV organs to HIV-positive pediatric patients in a consistent manner. Board Leadership asked the Ethics Committee for feedback on whether this should be done as a one-off variation; specifically, whether one patient should get a waiver to receive an organ donation (resulting in an individual IRB variance), or whether the entire HIV-positive pediatric patient population should get access to HIV-positive organs instead.

The Ethics Committee felt that it was important to ensure that all HIV-positive pediatric patients have IRB approval to access HIV-positive organs .

The DTAC collaborated with Board Leadership to formalize ideas for this approach. The approach should not be applied to thoracic organs yet considering that the report on the Thoracic Organ HOPE Act has not been completed yet. Institutional IRBs for pediatric research will follow the research structure for the HOPE Act for adult research.

Board Leadership is in the process of developing a formal proposal for HRSA, which will then be circulated to the full Board for more discussion before proceeding. The Board agreed on the importance of doing their due diligence to identify a solution for this pediatric patient. However, due to the patient's time-limited visa, they may not be able to help the patient in time, but hope that these actions will help future pediatric patients.

### **Closed Session**

The Board met in a closed session.