

# OPTN Board of Directors Meeting Summary

## Meeting Information: Agenda and Attendees

Thursday, May 15, 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 **May 15, 2025, 1:00–3:00 p.m. ET**.

### Agenda

#### Open Session

- Welcome and Announcements
- Introduction of New Board Members – Patient, Donor, and Family Representatives
- Histocompatibility Committee – Update to Histocompatibility Labs Policy and Bylaws Guidance Document
- INVEST Tax Filing
- Update on HRSA Directives
  - Allocating Organs Out of Sequence (AOOS)
  - Normothermic Regional Profusion (NRP)
  - Donor Derived Transmission Event
- Monitoring Report of the Modify Offer Acceptance Limits Policy
- Finance Committee Update

#### Closed Session

- The Board met in a closed session.

### Attendees

Attendee Name(s)	Affiliation
Richard Formica, A.Osama Gaber, Andrea Tietjen, Andrew Kao, Betsy Walsh, Calvin Henry, Caroline Alquist, Catherine Kling, Colleen McCarthy, Deborah Adey, Dev Desai, Dianne LaPointe Rudow, Emily Blumberg, Erika Demars, Garrett Erdle, George Surratt, Glen Kelley, J. David Vega, Katrina Fields, Laura Butler, Lloyd Ratner, Mandy Nathan, Martha Pavlakis, Michael Kwan, Nancy Metzler, Patrick Northrup, Robert Harland, Sandra Amaral, Sara Rasmussen, Tonya Gomez, Vicky Young	OPTN Board of Directors
Aite Aigbe, Frank Holloman, Joni Mills, Marilyn Levi, Patrick Mauro, Raymond Lynch, Shantel Delgado, Stephanie Grosser, Steve Keenan	HRSA Representatives

Attendee Name(s)	Affiliation
Christine Jones, Becca Fritz, Christine Sledge, Eli Greenspan, Emily Elstad, George Barnette, Jadyn Dunning, James Montgomery, Karen Edwards, Kristen Welker-Hood, Lee Thompson, Mary Lavelle, Melanie Bartlett, Rachel Shapiro, Samuel Hoff, Tamika Cowans, Taylor Melanson, Tennille Daniels, Tessa Kieffer, Thomas Barker, Zulma Solis	OPTN Board Support Staff
Alina Martinez, Betsy Warnick, Ethan Studenic, Krissy Laurie, Lauren Mauk, Liz Robbins Callahan, Tina Rhoades, Rebecca Murdock	OPTN Operations Contractor Staff
Rexanah Wyse Morrisette	OPTN Interim Executive Director
Cliff Miles, Kyle Herber	MPSC Representatives
Gerald Morris, PJ Geraghty	OPTN Committee Representatives
Allyson Hart, Jon Snyder	SRTR Representatives

## Meeting Summary

### Welcome and Announcements

The Board President welcomed attendees and began the meeting.

### Introduction of New Board Members – Patient, Donor, and Family Representatives

On 5/2 the Board of Directors met during an ad hoc meeting to vote to appoint eight new patient representatives to the Board. The final voting results were: 24 approve, 0 reject, 0 abstain. During this meeting, 7 of the 8 new members below were present and introduced themselves.

1. Garrett Erdle – located in Alexandria, Virginia (Region 11); past Chair of Patient Affairs Committee; kidney donor
2. Kartina Fields – located in Cincinnati, Ohio (Region 11); Pediatric Transplant Committee; mother of pediatric kidney recipient
3. Tonya Gomez – located in Archbold, Ohio (Region 10); Patient Affairs Committee; lung transplant recipient
4. Calvin Henry – located in Dacula, Georgia (Region 3); Patient Affairs Committee; served as a patient representative for American Society of Transplantation, and Scientific Registry of Transplant Recipients; lung transplant recipient
5. Amanda Nathan – located in Houston, Texas (Region 4); Heart Transplant Committee; heart transplant recipient
6. Elizabeth Schumacher\* -- located in Chicago, Illinois (Region 7); Previous Board experience; kidney transplant recipient
7. Betsy Walsh – located in Charlotte, North Carolina (Region 11); previous Board President; kidney donor

8. Vicky Young – located in Prescott, Arizona (Region 5); living kidney donor; family member of deceased donor

\*Elizabeth Schumacher was not able to attend the meeting.

The Board President welcomed the newly appointed Board members and thanked the Nominating Committee Chair and members for their work to fill the vacant seats of the eight patient representatives.

### ***Histocompatibility Committee – Update to Histocompatibility Labs Policy and Bylaws Guidance Document***

The Chair of the Histocompatibility Committee provided an update on the Histocompatibility Labs Policy and Bylaws Guidance Document. The Chair shared that in December 2024, the Centers for Medicaid and Medicare Services (CMS) implemented changes under the Clinical Laboratory Improvement Amendments (CLIA) program for how laboratories operations processes.

The committee included relevant OPTN policies addressed in updated policy in a public comment. The committee received Board approval in December 2024. On December 26, 2024, CMS released additional guidance that required the committee to make a minor update to the related OPTN Guidance Document to maintain alignment between CMS and the OPTN.

The original language reads as follows:

#### ***C.2.C #9: The frequency of periodic sample collection***

It is recommended that laboratories collect serum samples at regular intervals for candidates and use these samples to develop an antibody history and facilitate final crossmatches.

The proposed clarification recommends that labs maintain monthly serum samples, rather than current serum sample collection at regular intervals. The committee recognizes that this effort may not reflect the medically appropriate application of resources depending on the timeline for a candidate waiting to receive an organ. Therefore, the committee recommended transplant labs and programs have this defined within their lab agreements and should do what they feel is medically appropriate.

The original language reads as follows:

#### ***C.2.C #9: The frequency of periodic sample collection***

It is recommended that laboratories collect serum samples at regular intervals for candidates and use these samples to develop an antibody history and facilitate final crossmatches.

The Board voted on the Histocompatibility Committee's recommendation:

RESOLVED, that the changes to *C.2.C #9: The frequency of periodic sample collection* in the *Guidance Document for OPTN Histocompatibility Laboratory Bylaws and Policies*, as set forth below, are hereby approved, effective May 15, 2025.

The voting results were: 31 approve, 0 decline, 0 abstain.

**INVEST Tax Filing**

The Board President provided an update on INVEST tax filing. As a nonprofit corporation incorporated in Delaware, the OPTN must file taxes each year. Since the OPTN is not an income generating entity, it must fill out a 990-N form. The Board Leadership has decided to engage a Certified Public Accountant (CPA) to complete the form, and the President would sign the form as the Principal Officer of the OPTN. The cost of retaining a CPA will come out of the OPTN budget. The President emphasized the importance of the Board setting precedent of having the form completed by a tax professional every year.

**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)**

A letter of complaint was submitted to the OPTN regarding patients on the waiting list being bypassed at a transplant center due to allocating organs out of sequence. AOOS has been increasing in frequency since the institution of a kidney allocation system (KAS250) and the concurrent beginning of the Centers for Medicare & Medicaid Services (CMS) metrics for Organ Procurement Organization (OPO) certification.

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.

On 5/13, HRSA requested the OPTN to develop an analytic definition for AOOS by **May 27, 2025**. The Vice President of the Board convened a work group including leadership from OPTN Committees (Membership and Professional Standards Committee (MPSC), Patient Affairs Committee (PAC), Ethics Committee, and Expedient Task Force) who have been looking into defining AOOS. The Vice President, Interim Executive Director, and various representatives from the Board Support Contractor and HRSA recently met to further specify HRSA's request for the work group. The Vice President shared that the work group will have to be incredibly thoughtful when developing the analytic definition for AOOS

considering that there are different allocation processes (i.e., warm ischemic time, logistics, quality) for different organs (e.g., kidneys are not allocated based on severity of illness, whereas other organs are).

HRSA highlighted that their definition of AOOS has been included in the critical comment process. The definition specifies that AOOS is organs being allocated out of compliance with the Final Rule and OPTN policies. The Board Leadership requested a one-week extension (deadline would extend to 6/3) from HRSA, but to date, HRSA has not granted an extension.

### ***HRSA Directive on Normothermic Regional Profusion (NRP)***

A critical comment was published in September 2024 from a recovery surgeon who was concerned that there was not a standardized practice for ensuring that cerebral blood flow had been occluded for individuals undergoing thorax and abdominal NRP. Prior to the HRSA Directive, Operations and Safety and OPO Committees were developing a guidance document for NRP best practices.

Subsequently, HRSA directed 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.

The Board Leadership collaborated with the Interim Executive Director, HRSA, and the Contractor staff to determine which committees will work on the various actions described in the plan submitted to HRSA. The OPTN successfully submitted the work plan to HRSA by the deadline. Once the OPTN receives a response from HRSA, they will start allocating work to the various committees that will work on this project.

A Board member shared that NRP has been of interest to the PAC over the past couple of years and anticipates that it will be a focus of the committee moving forward. The Board member also highlighted the importance of involving the Ethics Committee in this work. The Board President agreed and acknowledged the Ethics Committee's efforts on previous HRSA directives.

### ***HRSA Directive on Donor Derived Transmission Event***

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. The Board President shared that if the OPTN were to eliminate all donors who answered “yes,” to the wild animal exposure question, it would eliminate approximately 170 donors or 440 organs from transplant eligibility. One Board member highlighted the importance of acknowledging that not all wild animals or exposures are identical (e.g., the incubation for period for rabies varies in immunosuppressed hosts). The Board member expressed her concern about how this information can be accurately and informatively captured and used as a decision-making tool. She also described the importance of educating medical providers about knowing the cause of death of donors who were exposed to rabies.

### ***Monitoring Report of the Modify Offer Acceptance Limits Policy***

A representative from the Operations Contractor provided an update on the Monitoring Report of the Modify Offer Acceptance Limits Policy. A summary of the presentation is as follows:

- In 2018, changes to OPTN policy established limits on the number of concurrent organ offer acceptances for any one candidate per organ type.
  - Concurrent acceptances still occurred after the implementation of these limits.
- The practice of having multiple primary organ offer acceptances can lead to late declines, which can cause logistical issues for OPOs.
- On May 29, 2024, the Modify Organ Offer Acceptance Limit policy was implemented. This policy reduced the number of primary organ offer acceptances from two to one for any one candidate per organ type.
- The data used included heart, liver, and lung candidate and transplant recipients (multiorgan transplants were excluded from the analyses).
  - Pre-policy period: November 29, 2023 – May 28, 2024
  - Post-policy period: May 29, 2024 – November 26, 2024
- 6,341 donors were recovered during the pre-policy period. 6,532 were recovered during the post-policy period.
  - Heart utilization and non-use rates by era and donor type
    - » 2,283 heart donors were recovered during the pre-policy period. 2,431 heart donors were recovered during the post-policy period.
  - Liver utilization and non-use rates by era and donor type

- » 5,986 liver donors were recovered during the pre-policy period. 6,119 liver donors were recovered during the post-policy period.
- Lung utilization and non-use rates by era and donor type
  - » 1,801 lung donors were recovered during the pre-policy period. 1,850 were recovered during the post-policy period.
  - » The utilization rate was defined as the percent of lungs that were transplanted based on all possible lungs from every deceased donor with at least one organ recovered for the purpose of transplant.

The contractor concluded the presentation by highlighting the following key takeaways:

- The utilization rate of heart and liver donors increased.
- There was an increase in the utilization rate of DBD lung donors and an increase in the non-use rate of DCD lung donors.
- The percent of accepted lung donors and accepted liver donors allocated out of sequence or via expedited placement increased post-implementation.
- The median cold ischemic time of livers increased post-implementation.
- Waiting list mortality rates did not change significantly for heart, liver, or lung candidates.

A Board member stated that the PAC has been tracking utilization rates and refusal codes. A few years ago, the PAC discussed the reliability of refusal codes that are being entered into the system for non-use donors. The Board President responded that he previously viewed a report out of the refusal codes, and it does not appear that OPOs were picking one refusal code only.

Two Board members discussed the importance of highly sensitized populations who have unique needs (i.e., pediatric candidates). They encouraged the contractor to consider pediatric candidates as a separate data set and investigate how the pre- and post-implementation era impacted those patients.

### ***Finance Committee Update***

The Board Treasurer provided a Finance Committee update. A summary of the update is as follows:

#### ***Finance Committee Tasks and Timeline***

- The Finance Committee is currently reviewing the remaining six months of the Fiscal Year (FY) 2025 budget (FY2025 began on October 1, 2024, and will end of September 30, 2025). The Treasurer shared that HRSA received additional resources through Modernization funding and has worked with the existing contractor to accommodate multiple contractors in a new modernized system.
- The Board will meet in late June to review and formally approve the FY2026 budget. The committee will hold office hours in advance of the meeting so that Board members have an opportunity to ask detailed questions.

***Finance Committee Charter***

- The committee is finalizing a Charter for the incoming Board/Finance Committee.

***FY2025 Budget Review***

- In July 2024, the Board recommended a fee increase, but it was not approved by HRSA. The committee will review the FY2025 budget to determine how the FY2026 budget will be structured with the existing listing fee amount, as the fee is based on every patient that is listed for transplantation and generates most of the revenue for OPTN operations.
- The committee and HRSA are discussing whether they anticipate any changes to the registration fee. They are working with the Operations Contractor to determine whether they are maximizing the use of the OPTN funds.

***FY2026 Budget***

- The committee will meet almost weekly to review the FY2025 budget draft and develop the FY2026 budget which is due to HRSA by 7/1. The current members of the Finance Committee will involve the new Board Leadership group in the meetings to ensure they are informed on the FY26 budget.

***OPTN Professional Service Fees***

- The Treasurer and Board President acknowledged the importance of specifying a dollar amount for OPTN Professional Service Fees (i.e., accounting, legal) within the budget to ensure that the OPTN has sufficient accounting and legal representation.

***Information Technology (IT) and Software Programs***

- The committee is reviewing IT and software expenses to ensure that any changes in these budget line items do not impact efforts and projects related to patient safety.

***Investment Policy Review***

- The Committee is reviewing whether there are any investment categories the OPTN should avoid investing in to ensure.

**Closed Session**

The Board met in a closed session.