OPTN Board of Directors Meeting Summary

Meeting Information: Agenda and Attendees

Thursday, March 20, 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 March 20, 2025, 1:00–3:00 p.m. ET.

Agenda

Open session

- Welcome and Announcements
- Public Comment Period Approval of HOPE Act
- Update on HRSA Directives: Allocation out of Sequence (AOOS) response, and Normothermic Regional Perfusion (NRP)
- Patient Affairs Committee – Patient Awareness of Listing Status (PALS) Update
- Revise Conditions for Access to the OPTN Computer System

Closed session

- The Board met in a closed session

Meeting Attendees

Attendee Name(s)	Affiliation
Richard Formica, Lloyd Ratner, Jenn Muriett, Andrea Tietjen, Andrew Kao, Catherine Kling, Christopher M. Jones, Colleen McCarthy, Deborah Adey, Deborah Levine, Denise Abbey, Dorrie Dils, Dr Caroline Alquist, Emily Blumberg, Gaurav Gupta, George Surratt, Glen Kelley, Jennifer Lau, Jennifer Reese, Julie Spear, Kelley Hitchman, Laura Butler, Martha Pavlakis, Michael Kwan, Nancy Metzler, Patrick Northup, Sandra Amaral, Sara Rasmussen	OPTN Board of Directors
Aite Aigbe, Arjun Naik, Frank Holloman Jim Bowman, Jon Mills, Kala Rochelle, Mesmin Germain, Patrick Mauro, Raymond Lynch, Shantel Delgado	HRSA Representatives
Christine Jones, Rachel Shapiro, Andrew London, Anthony LaBarrie, Becca Fritz, Christine Sledge, Eli Greenspan, Emily Elstad, George Barnette, Jadyn Dunning, James Montgomery, Karen Edwards, Lee Thompson, Lori Downing, Mary Lavelle, Tennille Daniels, Tessa Kieffer, Thomas Barker, Vanessa Amankwaa	OPTN Board Support Staff
Stephanie Pouch, MD, Disease Transmission Advisory Committee, Chair Andrew Kao, MD, Network Operations Oversight Committee, Chair Kyle Herber, Membership and Professional Standards Committee (MPSC), At-Large Member	Presenters

Attendee Name(s)	Affiliation
Patient Affairs Committee: Lorrinda Gray-Davis, Michael Brown Policy Oversight Committee: Allyson Hart Transplant Coordinators Committee: Christine Brenner	Committee Members
Betsy Warnick, Cole Fox, Desiree Tenenbaum, Emy Trende, Krissy Laurie, Lindsay Larkin, Matt Cafarella, Tina Rhoades, Tynisha Smith	OPTN Operations Contractor Staff
Roslyn Mannon, Ryutaro Hirose	SRTR Leadership
Rexanah Wyse Morrissette	OPTN Interim Executive Director

Meeting Summary

Welcome and Opening Remarks

The Board President welcomed attendees and began the meeting.

Public Comment Period Approval of HOPE Act

Representatives from the OPTN Disease Transmission Advisory Committee (DTAC) and Operations Contractor presented an overview of the public comment period approval of the HIV Organ Policy Equity Act (HOPE Act). A summary of the presentation is as follows:

- The HOPE Act was enacted in November 2013 and allowed for research to be conducted regarding the safety and outcomes of solid organ transplantation from donors with HIV to recipients living with HIV at programs that participate in an Institutional Review Board (IRB) approved research protocol in keeping with research criteria that had been published by the U.S. Department of Health and Human Services (HHS) through National Institutes of Health (NIH). The effort to increase access for candidates living with HIV has been very successful. There have been over 500 transplants of organs from donors with HIV to recipients living with HIV and no patient safety events.
- On November 27, 2024, HHS amended the OPTN Final Rule to remove research requirements for transplantation of kidneys, livers and liver kidneys from donors of HIV to recipients living with HIV. Subsequently, on December 30, 2024, NIH issued a final notice in the Federal Register to modify research criteria for non-kidney, non-liver organs from donors with HIV to recipients living with HIV (following a public comment period). In January 2025, HRSA directed (on behalf of the HHS Secretary) that changes be implemented in OPTN policy to align with the amended OPTN final rule and NIH final notice on an accelerated time frame. From January through February, the DTAC has been reviewing and developing proposed changes to OPTN policy accordingly.
- In accordance with the amended OPTN final rule and NIH final notice, and consistent with HRSA's directive, modifications to OPTN policy for transplantation of organs from donors with HIV to recipients living with HIV include the following:
  - Adjustments to reflect that kidney, liver and liver-kidney organs no longer need to meet research criteria or be conducted through an open variance for HIV transplantation.

  - Non-stigmatizing language use throughout, consistent with terminology in Final Notice.
- This proposal aims to ensure patient safety is maintained by adding the following safeguards for liver kidney and liver kidney candidates:
  - Documentation in the medical record must be pursued by a transplant physician regarding the candidate's HIV status and the candidate's willingness to accept an organ from donors with HIV. This must occur prior to the double verification process that already exists in policy.
  - A transplant physician must be the individual who verifies candidate HIV status and willingness to accept an organ from a donor with HIV after the donor is found to have a positive HIV test (this informed consent process is already in policy, but the fact that a transplant physician must obtain the informed consent is new). This applies to false positive tests as well. A transplant physician would verify the status and then that would be confirmed upon a site survey follow up visit whenever that occurs.

The proposal outlines that a transplant surgeon and other licensed healthcare professionals attest to the candidate HIV status and the candidate's willingness to accept an organ from a donor with HIV prior to or upon receipt for transplantation (this is a new requirement and would be documented in the medical record). This proposal does not change the requirements for participation in the variance and to meet NIH research criteria for transplantation of non-kidney and non-liver organs from donors with HIV to candidates with living with HIV. However, the NIH Final Notice does relax some of the criteria for programs to be eligible for participation in research protocols for these transplant procedures.

The resource estimates for this project from development, implementation and ongoing stratified by fiscal year total just over $160,000, spread out from November 2024 (the beginning of the project) until June 2028. Development includes everything up until Board approval; implementation is the effort to implement the proposal; and ongoing means if the project continues on an annual basis moving forward, (member support, monitoring, and post-implementation evaluation).

The Policy Oversight Committee (POC) estimates this project to be a high cost, high benefit project based on metrics used to evaluate its success (i.e., waiting list registrations/removals, number of transplants, post-transplant graft/patient survival, and non-use and utilization rates). The POC supports this project moving forward for public comment (voting results: 14 yes, 0 no, and 0 abstain).

The Board approved the following public comment item as recommended by the POC:

> Revisions to Human Immunodeficiency Virus (HIV) Policies to Align with Federal Regulatory Updates

Final Vote: 27 approve, 0 reject, and 0 abstain

Update on HRSA Directives: Allocation out of Sequence (AOOS) response, and Normothermic Regional Perfusion (NRP)

The Board President provided an update on the AOOS response, and NRP.

The letter on the AOOS response directs the OPTN to complete the following by March 31, 2025:

- 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 variance11 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.

The Board emphasized the importance of public transparency regarding how frequently patients are excluded from access to organs when matches have been made out of sequence.

The letter on NRP 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
- Proposed OPTN data collection regarding the attempted and/or successful use of NRP in patients from whom organs may be procured

NRP in the United States is an emerging technology that has great potential to increase organ utilization and use that will have a direct impact on patients with organ failure and donor families. NRP has become rapidly adopted nationwide, so the OPTN, HRSA and UNOS will need to continue to develop standardized practices around ensuring that any potential donor who is exposed to NRP as a recovery option is neurologically passed away. Considering that this will be a large project, the Board emphasized the importance of leveraging existing work (e.g., AOOS work). At the Board's request, the Operations and Safety Committee and the Organ Procurement Organization (OPO) Committee developed a guidance document for a two-step/person verification process which would help ensure that cerebral blood flow has been interrupted.

Patient Affairs Committee (PAC) – Patient Awareness of Listing Status (PALS) Update

In 2016, there was an active discussion about whether transplant programs should be informing patients when they're made active and inactive. Given the technology at the time, this didn't seem like an achievable task and was felt to be overly cumbersome to transplant programs. The Board discussed an overview of the PALS project to date including next steps.

- Patient Awareness of Listing Status (PALS) Project Kickoff - July 9, 2024
  - Acknowledged this issue was raised in 2014 but the technology was not readily available.
  - Neither CMS nor OPTN policy currently require notification of inactive status. A first step to advance this effort would be a policy requirement for transplant programs. This pathway was recommended by HRSA and OPTN contractor staff.

- PAC subcommittee explored several pathways to execute the project:
  - Policy requirement for transplant programs to notify candidates of changes to waiting list status.
  - Policy requirement plus possible changes to existing Application Programming Interface (API) to provide waiting list status in real-time.
  - Development of an OPTN smartphone application to share information directly to transplant candidates.
- OPTN representatives recommended the PALS subcommittee advance the project to the Policy Oversight Committee (POC) while simultaneously developing the application.
  - Subcommittee declined the recommendation and asked to advance the project proposal to the Board.
- PALS project was presented to Executive Committee on November 14, 2024.
  - Executive Committee agreed with recommendation to advance project through the POC.
- Follow-up discussions occurred with Board Leadership and Executive Committee around involving the Transplant Administrators Committee (TAC) and the Transplant Coordinators Committee (TCC) in the policy development aspect of the project.

The Board, the Executive Committee, and Board Leadership strongly supports patients being aware of their waiting list status, specifically active or inactive, and that it is a fundamentally important topic that needs to be addressed. Current policy states that transplant centers need to notify patients upon listing and list removal.

Next steps for the PALS Project include:

- Agreement among Board Leadership and Executive Committee that the project should have a formal policy development component.
- TAC and TCC leadership are willing to support policy development for the PALS project under an expedited 6-month timeline, and have begun drafting policy language.
- Communicate to the PAC the decision to involve the TAC and TCC in the PALS project and reinforce the importance of a policy to support development and use of a notification application.

The Board discussed possible elements of this project, including the proposal to use a “yellow light” instead of a “red light” to represent an inactive status. Many patients confuse inactive status with being off of the list. Enhancements could be made to this technology approach in the future.

The Board also discussed an expedited public comment period for the project, a baseline for patient access, details about how the technology platform would work, utilizing the feedback that comes out of public comment, budgeting processes, and the impact on patients’ mental health from lack of notification of inactive status.

The Board discussed the importance of following the OPTN’s well-established policies and processes (i.e., the Board requesting HRSA to distribute a Task Order build out the technology approach).

Revise Conditions for Access to the OPTN Computer System

The Chair of the Network Operations Oversight Committee (NOOC) presented an overview on the policy project about what parties have access to the OPTN computer system. A summary of the presentation is as follows:

- The policy intends to restrict access to OPTN computer system to protect the confidential and patient-identified data. The policy was sent out for public comment in the summer of 2024 and was approved on December 3, 2024. The NOOC reviewed the implementation plan in February 2025, and the policy was slated for implementation on March 27, 2025.
- The policy removed "placing organs for purposes other than transplant" from the list of permissible reasons for access. Under the policy, the permissible reasons for access to the OPTN computer system are:
  - Facilitating organ transplants
  - QAPI purposes
  - Fulfilling OPTN obligations
- Access to the system for placement of organs for purposes other than transplantation (e.g., for research) was specifically prohibited as part of the proposal. This decision was informed by the following factors:
  - The Final Rule requires the protections of patient-identified data when used for research purposes, which would necessitate additional security controls.
  - Data provided via the OPTN computer system gives more than the minimum necessary standard to accomplish the researcher's goal of placement of the organ, so there is no way to restrict access to a particular patient when using the OPTN computer system
  - There are established processes for sharing patient-identified data for research purposes outside of the OPTN computer system.
  - Research or scientific organizations (RSOs) have external systems to retain OPTN data with no security assessment or oversight, and there are no contractual obligations between RSOs and the OPTN, which results in no OPTN data oversight.
- At least one RSO raised concerns about being restricted from the OPTN computer system; however, the removal of RSOs from the computer system does not stop their ability to place organs for research purposes.
- HRSA initially suggested pausing the implementation that had been set for March 27, 2025. NOOC prefers to proceed with the scheduled implementation in the interest of protecting the OPTN computer system and its patient and donor data, and simultaneously determine another pathway for RSOs to access the data they need to continue their research.

The Board discussed the importance of both preventing security breaches as well as serving the transplant community effectively. The policy does not currently include data use agreements (DUAs) that can be set up between the OPTN and the RSOs. Representatives from NOOC and UNOS clarified

that RSOs would not be able to receive organ offers from OPOs via DonorNet for research purposes. However, there is an available mechanism for entities outside the OPTN to make a data request, which was put in place for research purposes. Representatives from NOOC encouraged HRSA and the Board to allow the implementation of the policy to continue as planned rather than halting implementation completely. NOOC representatives agreed that the policy may need to be amended in some way to account for RSOs that need access to certain data sets.

Board members who are affiliated with OPOs noted that a majority of organs donated are backed up to research entities even if they are intended for transplant, so that if there is an issue with transplantation the offer can be made to research partners. Restricting RSO access to the OPTN computer system would require OPO staff to make phone offers to RSOs with the patient information, and collecting data retrospectively via a data request may not provide the critical information that an RSO needs.

HRSA acknowledged the gravity of the issues presented and the potential for losing organs that could be used for research due to these data restrictions. HRSA encouraged the Board to vote on a resolution today to defer implementation of the policy while NOOC determines a path forward for ensuring data security for parties using the OPTN computer system for research, while not impacting utilization. The Board President and NOOC Chair expressed a preference for implementing the policy for business entities and pausing the restrictions on access for research purposes until NOOC can address the discussed issues in an additional policy.

The Board decided to delay the implementation of permissible use of access to the data system for 90 days, with the ability to revisit another deferment if the policy update is not completed within the timeframe. The intention of this deferment is to allow research to continue without interruption. The Board voted on the following action:

> Implement the Revise Conditions for Access and Reporting Privacy Incidents to the OPTN Computer System policy as scheduled on March 27th but will defer the implementation of permissible use of access to data system for 90 days to allow research to continue with the ability to revisit another deferment if policy update is not completed.

Final Vote: 32 approve, 0 reject, 0 abstain.

NOOC will work to update the policy to respond to concerns about data access restrictions for research purposes. HRSA will provide more detailed guidance to NOOC about incorporating data use agreements into the policy update.

A notification will be sent to members to alert them to the delay in implementing permissible use of access to the system and explain the Board's rationale for this decision.

The Board opted to defer discussion of the updates to the eGFR policies until the next Board meeting.

The open session of the Board meeting concluded.

Closed Session

The Board met in a closed session.