

OPTN Board of Directors Meeting: Executive Summary

Meeting Information: Agenda and Attendees

June 9-10, 2025 | Location of Event: Zoom

The following is an executive summary from the OPTN Board of Directors meeting, which took place on **June 9, 2025, 1:00–7:00 p.m. ET and June 10, 2025, 12:30–6:30 p.m. ET.**

Agenda – June 9, 2025

Open Session

- President’s Welcome and Introductions
- Call to Purpose
- Operational Rules of Engagement
- Consent Agenda
- President’s Report to the Board
- Escalation of Status for Time on Left Ventricular Assist Device
- Heart Committee Emergency Project Request
- Monitor Ongoing eGFR Modification Policy Requirements
- HRSA Address

Closed Session

- The Board met in a closed session.

Agenda – June 10, 2025

Open Session

- Welcome and Announcements
- Finance Committee Report to the Board (Part 1)
- Revisions to Human Immunodeficiency Virus (HIV) Policies to Align with Federal Regulatory Updates
- Clarify Requirements for Reporting a Potential Disease Transmission
- Finance Committee Report to the Board (Part 2)
- Modify Lung Donor Data Collection

- Policy Oversight Committee (POC) New Project Approvals
- Network Operations and Oversight Committee (NOOC) Report to the Board

Executive Summary: Day 1

President's Welcome and Introductions

The Board President welcomed attendees and began the meeting.

Call to Purpose

A patient representative on the OPTN Board opened the meeting by presenting a call to purpose to honor the gifts of donation and transplantation that the OPTN Board and patient community have received. The call to purpose featured a [brief video](#) that highlighted a pediatric kidney recipient whose prenatal condition led him into the world of organ donation and transplantation. The patient representative thanked the OPTN Board and community for allowing him to serve a greater calling and purpose during his tenure on the Board.

Operational Rules of Engagement

The Board Support Contractor shared best practices for virtual meeting participation and reminded incoming Board members to stay in listen only mode during presentations and deliberations and to hold questions until after voting actions concluded.

Consent Agenda

The Board President presented two consent agenda items to the Board. The consent agenda consists of items that are non-controversial regarding their content and in how they were received during public comment. After presenting both consent agenda items, the Board President asked for and received two motions to approve the consent agenda.

The Board approved the two items on the consent agenda:

- Barriers Related to the Evaluation and Follow-Up of International Living Donors
- Updates to National Liver Review Board (NLRB) Guidance & Further Alignment with Liver Imaging Reporting and Data System (LI-RADS)

Final Vote: 31 approve, 0 reject, and 0 abstain

President's Report to the Board

The President of Board gave an overview of the Board's work in the past six months, including the Board's efforts to support the OPTN and modernization initiative, ensuring the patient's voice is front and center by addressing critical patient issues, approving policy projects brought forth by Committees to update, modify, and/or enhance OPTN policies and procedures, and responding to three HRSA directives, including allocating organs out of sequence, a plan for using normothermic regional perfusion (NRP) in patients from whom organs may be procured, and work to support actions and policy related to donor derived transmission events.

Escalation of Status for Time on Left Ventricular Assist Device

The Heart Transplantation Committee Chair presented a policy proposal titled *Escalation of Status for Time on Left Ventricular Assist Device*. The purpose of the proposal is to increase access for adult heart candidates with a Left Ventricular Assist Device (LVAD). With this proposal, the Heart Transplantation Committee seeks to provide a time-based pathway to give greater priority to LVAD supported adult candidates on the wait list; increase transplant opportunities for LVAD supported candidates prior to device complication; and transplant stable candidates and improve post-transplant outcomes.

The Board voted on the Heart Transplantation Committee's recommendation:

RESOLVED, that the changes to OPTN Policies 6.1.B.vii: Dischargeable Left Ventricular Assist Device (LVAD) Support for Eight or More Years and Policy 6.1.C.xiv: Dischargeable Left Ventricular Assist Device (LVAD) Support for Six or More Years as set forth in Exhibit A below, are hereby approved, effective pending notice and implementation.

FURTHER RESOLVED, the OPTN Heart Committee is directed to recommend to the OPTN Board a sunset date for the changes set forth in Exhibit A, based on review of at least six months of available data, following the implementation of the changes set forth in Exhibit A.

FURTHER RESOLVED, if the Heart Committee's recommendation for a sunset date of the language in Exhibit A is not amended or rejected by the OPTN Board within three months from the date of its submission, the recommendation shall be considered adopted by the OPTN Board and the language in Exhibit A will sunset on the date recommended by the OPTN Heart Committee.

FURTHER RESOLVED, that the changes to *OPTN Policies 6.1.B.vii: Dischargeable Left Ventricular Assist Device (LVAD) Support for Eight or More Years and 6.1.C.xiv: Dischargeable Left Ventricular Assist Device (LVAD) Support for Six or More Years* as set forth in Exhibit B below, are hereby approved, effective upon the sunset of the changes in Exhibit A.

Final Vote: 30 approve, 0 reject, and 0 abstain

Heart Committee Emergency Project Request

The Heart Transplantation Committee Chair presented an emergency measure to modify guidance for pediatric heart exception requests to address the temporary mechanical circulatory support (MCS) equipment shortage. The purpose of the emergency project request is to respond to the potential pediatric patient safety risk associated with the shortage of pediatric MSC devices and support equipment and to prevent inequities that may arise if exception requests were unevenly requested or granted. Under this request, the pediatric guidance document would be updated to identify circumstances by which pediatric dilated cardiomyopathy (DCM) candidates, for whom timely access to mechanical circulatory support is limited due to the ongoing device and support shortage, may be eligible for status 1A by exception.

The Board voted on the Heart Transplantation Committee's recommendation:

RESOLVED, that the following emergency action is required due to patient safety factors and is thereby authorized by *OPTN Management and Membership Policy E.7: Emergency Actions*

FURTHER RESOLVED, that the changes to the *Guidance for Pediatric Heart Exception Requests*, as set forth below, are hereby approved, effective June 12, 2025, and shall expire on June 11, 2026.

FURTHER RESOLVED, that the OPTN Heart Transplantation Committee will re-evaluate the shortage of MCS devices and supporting equipment and recommend to the OPTN Board whether the guidance update needs to remain in effect by September 10, 2025.

Final Vote: 31 approve, 0 reject, and 0 abstain

Monitor Ongoing eGFR Modification Policy Requirements

The Vice Chair of the Minority Affairs Committee (MAC) presented a policy proposal to update and enhance ongoing policy requirements regarding wait time modifications for kidney candidates affected by race inclusive of eGFR calculations. Under this proposal, programs would have a written protocol and maintain documentation for confirming candidate race, fulfilling notification requirements, and seeking supporting documentation. Following the MAC Vice Chair's presentation, the Board discussed the inclusion of educational materials in retrospective notification, the eventual obsolescence of the policy, and the timeline needed programs to comply with the policy. One Board member suggesting shortening the timeline for compliance by six months.

Prior to voting on the MAC recommendation, the Board voted on an amendment to the third resolution which would have changed the compliance date from September 11, 2026 to March 11, 2026.

FURTHER RESOLVED, the OPTN Board encourages all transplant programs to prioritize compliance with the requirements in OPTN *Policy 3.7.D* (development and documentation of protocols) and *Policy 3.7.D.i* (retrospective notification requirements) adopted at this Board meeting as soon as possible, but no later than ~~September 11, 2026~~ March 11, 2026.

This amendment did not pass. Amendment Vote: 6 approve, 21 reject, and 3 abstain

The Board then voted on the Minority Affairs Committee's recommendation with the original compliance date of September 11, 2026:

RESOLVED, that the changes to *OPTN Policies 3.7.D: Waiting Time Modifications for Kidney Candidates Affected by Race Inclusive eGFR Calculations, 3.7.D.ii: Determination of Eligible Candidates, 3.7.D.iii: Application for Waiting Time Modification, and 3.7.D.iv: Reporting Requirements for Kidney Transplant Programs*, as set forth below, are hereby approved, effective September 10, 2025.

FURTHER RESOLVED, that the changes to *OPTN Policy 3.7.D.i: Notification Requirement*, as set forth below, are hereby approved, effective January 4, 2024.

FURTHER RESOLVED, the OPTN Board encourages all transplant programs to prioritize compliance with the requirements in OPTN *Policy 3.7.D* (development and documentation of protocols) and *Policy 3.7.D.i* (retrospective notification requirements) adopted at this Board meeting as soon as possible, but no later than September 11, 2026.

Final Vote: 28 approve, 1 reject, and 2 abstain

HRSA Address

HRSA presented an update on OPTN Modernization efforts, which highlighted the process and outcome of the Special Election, improvements in patient safety efforts, including organs allocated out of sequence (AOOS), and strengthening safeguards in organ procurement. HRSA shared details on their OPTN Modernization Discovery findings and plans for OPTN registration fees, and stated their future goals for OPTN Modernization, which included improvements in governance, patient safety, and OPTN operations.

Closed Session

The Board met in a closed session.

Executive Summary: Day 2

Welcome and Announcements

The Board President welcomed attendees and began the meeting.

Finance Committee Report to the Board (Part 1)

The Treasurer presented opportunities for immediate (Q4) cost reductions or savings to meet the revenue budget for fiscal year (FY) 2025. When the Finance Committee met for the first time this year, they faced a \$3,000,000 shortfall due to increased litigation and operations fees under a fixed registration fee, and after reducing staffing and purchase service costs, anticipate a \$1,400,000 shortfall at the end of FY 2025. The Treasurer presented opportunities for additional cost savings in FY 2025 to reduce the shortfall, including prioritization of critical patient projects as identified by the Policy Oversight Committee (POC), discontinuing non-critical committee meeting support for Q4, and pausing new work on continuous distribution and site surveys for Q4.

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

The Disease Transmission Advisory Committee Chair presented a policy proposal that would align OPTN policy with the amended OPTN Final Rule and NIH Final Notice regarding the removal of research requirements for transplantation of kidneys and livers from donors with HIV. The proposal would also ensure patient safety is maintained while access expands for individuals living with HIV by allowing transplants of livers, kidneys, and liver-kidneys from donors with HIV to candidates living with HIV without requiring participation in NIH research criteria or OPTN HIV Organ Policy Equity Act (HOPE) Act variance. Following the presentation, the Board discussed which clinicians would be responsible for documentation and what IRB would be used.

The Board voted on the Disease Transmission Advisory Committee's recommendation:

RESOLVED, that the changes to OPTN Policies 1.2: Definitions, 2.7: HIV Screening of Potential Deceased Donors, 2.7.A: Exceptions to HIV Screening Requirement, 5.3.B: Infectious Disease Screening Criteria, 5.3.D: Liver Acceptance Criteria, 5.3.H: Kidney Offer Filters, 5.4.E: Allocation to Candidates Not on the Match Run, 5.5.C: OPO Requirements for Positive HIV Results, 5.8.A: Pre-Transplant Verification Prior to Organ Receipt, 5.8.B: Pre-Transplant Verification Upon Organ Receipt, 14.3: Informed Consent Requirements, 14.4.E: Living Donor Exclusion Criteria, 15.2: Candidate Pre-Transplant Infectious Disease Reporting and Testing Requirements, 15.3.B: Donors

with Risk Identified Pre-Transplant, 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors, 15.7.A: Requirements for Allocating HIV Positive Deceased Donor Organs, 15.7.B: Requirements for Allocating HIV Positive Living Donor Organs, 15.7.C: Transplant Hospital Requirements for Transplantation of HIV Positive Organs, and 16.6.A: Extra Vessels Use and Sharing, as set forth below, are hereby approved, effective June 26, 2025.

Final Vote: 30 approve, 0 reject, and 0 abstain

Clarify Requirements for Reporting a Potential Disease Transmission

The Chair of the Disease Transmission Advisory Committee presented on a proposal to clarify transplant programs' reporting requirements when there is discovery of a potential transmission of unexpected pathogen, disease, or malignancy and distinguish between lung recipients showing clinical evidence of infection and lung recipients with evidence of colonization but not showing evidence of infection to ascertain the necessity of reporting and to ensure patient safety concerns are communicated. The proposed updates align with the strategic plan to enhance OPTN efficiency by clarifying reporting requirements to further improve the accuracy of reporting of potential disease transmission. The project aims to clarify the policy reporting requirements process to make the process more efficient by accurately and timely reporting a potential disease transmission.

The Board voted on the Disease Transmission Advisory Committee's recommendation:

RESOLVED, that the changes to *OPTN Policies 15.5: Transplant Program Requirements for Communicating Post Transplant Discovery of Disease or Malignancy, 15.5.A: Transplant Program Requirements for Post Transplant Discovery of Donor Disease or Malignancy, 15.5.B: Transplant Program Requirements for Reporting Post Transplant Discovery of Recipient Disease or Malignancy* as set forth below, are hereby approved, effective August 1.

Final Vote: 30 approve, 0 reject, and 0 abstain

Finance Committee Report to the Board (Part 2)

The Finance Committee proposed four potential resolutions to vote on for cost reductions or savings in Q4 including discontinuation of non-critical meeting support, pausing virtual site visits, pausing new work on continuous distribution, and approving POC recommendations for savings identified by the POC prioritization tool. Multiple Board members expressed concerns about pausing continuous distribution and other projects identified by the POC prioritization tool.

The Board voted on the Finance Committee's recommendation:

RESOLVED, that pursuant to the recommendation of the Finance Committee, the Board hereby approves the discontinuation of non-critical meeting support for the fourth quarter of 2025.

Final Vote: 31 approve, 0 reject, and 1 abstain

The Board voted on the Finance Committee's recommendation:

RESOLVED, that pursuant to the recommendation of the Finance Committee, the Board hereby approves pausing virtual site visits in the fourth quarter of 2025;

FURTHER RESOLVED, that pursuant to the recommendation of the Finance Committee, the Board hereby requests that OPTN send out a communication about the most frequent issues identified in the last 2-3 years of site visits as a general compliance reminder.

Final Vote: 30 approve, 2 reject, and 0 abstain

Modify Lung Donor Data Collection

The Chair of the Lung Transplantation Committee presented on a proposal to improve lung allocation efficiency and streamline communication between organ procurement organizations and lung transplant programs by enhancing OPTN data collection. If the completeness of data for organ offers received by lung transplant programs improves, these programs will be able to review/respond to offers more quickly and accept organs earlier in the allocation process.

The Board voted on the Lung Transplantation Committee's recommendation:

RESOLVED, that the changes to *OPTN Policy 2.11: Required Information for Deceased Lung Donors* as set forth below, are hereby approved, effective pending notice and implementation.

FURTHER RESOLVED, that the changes to data collected by the OPTN, as set forth below, are hereby approved, effective pending notice and implementation.

Final Vote: 27 approve, 3 reject, and 1 abstain

Policy Oversight Committee (POC) New Project Approvals

The Policy Oversight Committee Chair introduced two new proposed projects: Require Patient Notifications for Inactive Status and Modify Lung Allocation by Candidate Biology.

The purpose of the Require Notifications for Inactive Status project is to promote transparency around waiting list status for patients, particularly regarding inactive status.

The Board voted on the Policy Oversight Committee's recommendation to approve the following new project:

- Require Patient Notifications for Inactive Status

Final Vote: 30 approve, 0 reject, and 0 abstain

The purpose of the Modify Lung Allocation by Candidate Biology project is to increase access to transplant for blood type O candidates, moderately short candidates, and candidates with multiple biological disadvantages to the extent possible relative to limitations of the donor pool, without negatively impacting waiting list mortality or post-transplant outcomes.

The Board voted on the Policy Oversight Committee's recommendation to approve the following new project:

- Modify Lung Allocation by Candidate Biology

Final Vote: 21 approve, 8 reject, and 0 abstain

Network Operations and Oversight Committee (NOOC) Report to the Board

The Chair of the Network Operations and Oversight Committee (NOOC) gave an update on the NOOC's work in the past year which included metrics and monitoring related to the performance of the OPTN computer system and OPTN member security policies. The presentation also included information about ongoing work of the NOOC, including evaluating computer system access for research and the best approach to maintain system security while ensuring appropriate levels of access, as well as working with HRSA to finalize details of a member Data Use Agreement.