

Thank you to everyone who attended the Region 2 Summer 2025 meeting. Your participation is critical to the OPTN policy development process.

Regional meeting <u>presentations and materials</u>

Public comment closes October 1<sup>st</sup>! Submit your comments

The sentiment and comments will be shared with the sponsoring committees and posted to the OPTN website.

# **Non-Discussion Agenda**

Modify Guidance for Pediatric Heart Exception Requests to Address Temporary Mechanical Circulatory Support Equipment Shortage

**Heart Transplantation Committee** 

Sentiment: 2 strongly support, 3 support, 7 neutral/abstain, 0 oppose, 0 strongly oppose

Comments: This was not discussed during the meeting, but attendees were able to submit comments with their sentiment. An attendee noted that this policy should only be limited to the time of the lack of temporary MCS and that pressure should be put on the manufacturers for this life saving therapy.

## **2025 Histocompatibility HLA Table Update**

Histocompatibility Committee

Sentiment: 2 strongly support, 7 support, 3 neutral/abstain, 0 oppose, 0 strongly oppose Comments: This was not discussed during the meeting, but attendees were able to submit comments with their sentiment. We must remember the science of testing and variability is not complete and individual labs and centers still need to allow for this to continue recipient patient specific virtual crossmatch.

# **Discussion Agenda**

## **Require West Nile Virus Seasonal Testing for All Donors**

Ad Hoc Disease Transmission Advisory Committee

Sentiment: 4 strongly support, 5 support, 1 neutral/abstain, 3 oppose, 0 strongly oppose Comments: Several attendees supported extending the turnaround window for WNV NAT testing in living donors to 10 days, noting that many NAT labs are send-outs and that a shorter timeframe is not practical. Others suggested requiring that living donor results be valid within 28 days of surgery, emphasizing that a 7-day requirement would be unrealistic, especially for emergent cases such as pediatric or acutely ill liver patients. There was disagreement on whether testing should be tied to the donor's date of hospital admission after July 1 versus applying to donors as of July 1. Some supported seasonal testing during periods of higher incidence, arguing that this would improve accuracy by reducing false positives. Others expressed concern that limiting testing to certain months does not



reflect shifting weather patterns or travel-related risks, particularly in regions like New Jersey where patients often move between climates. These attendees advocated for year-round testing to ensure broader safety. Operational challenges were highlighted, particularly for deceased donors, where results would often not be available before the transplant occurred. This raised concerns about the practical application of the policy in urgent allocation scenarios.

## **Update and Improve Efficiency in Living Donor Data Collection**

## **Living Donor Committee**

#### Sentiment: 2 strongly support, 9 support, 1 neutral/abstain, 1 oppose, 0 strongly oppose

Comments: Questions were asked about the need for the OPTN forms if SRTR can already use data linkages, and whether clinic data would be required on the Non-Donation form. If so, clarification was requested on who would be responsible for ordering and reporting such tests. Attendees emphasized that more detailed information is needed to understand the scope and expectations. Concerns were expressed that if data collection is not required, some institutions may stop supporting these activities, even if centers wish to continue them. Additional uncertainty was noted about the SRTR's role, since it is a private contractor and may not sustain this function long term. Some attendees warned that reducing mandatory follow-up from two years to a voluntary process could risk losing critical outcome data, limiting the ability to monitor donor safety, identify long-term complications, and maintain transparency. Others highlighted that improved long-term data collection could be beneficial, both in extending beyond the current two-year window and in capturing barriers to donation among those who do not proceed. Operational and ethical concerns were also raised. Attendees noted that the process could be burdensome, particularly for individuals who did not proceed to donation, who may feel pressured, disappointed, or reluctant to respond to follow-up requests. They emphasized that centers would need compensation to offset the added regulatory workload. The timing of donor interactions varies across programs, which adds confusion about when and how data should be collected. Attendees also referenced the growing involvement of third-party and commercial organizations in the living donor space, complicating responsibilities and expectations. Finally, there were questions about how SRTR would secure sufficient funding to sustain long-term donor follow-up activities.

#### **Require Patient Notification for Waitlist Status Changes**

#### **Transplant Coordinators Committee**

#### Sentiment: 5 strongly support, 6 support, 1 neutral/abstain, 1 oppose, 0 strongly oppose

Comments: Several attendees noted that written notification may not be the most effective approach, especially when patients are reactivated before an inactivation letter could reasonably be delivered. They emphasized that best practices include timely communication through MyChart, phone calls, or inperson discussions with patients and families. Questions were raised about whether a letter would be required each time a patient changes from active to inactive status and back again, and whether notifications must also extend to nephrologists or other care providers in addition to the patient. Others argued that letters serve an important role, since phone calls can be missed, not all patients have access to MyChart, and some facilities do not offer electronic portals. These attendees saw little downside to letters as a supplemental form of communication. Concerns were raised that the proposal could

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unintentionally increase the number of "internal hold" candidates, especially at extra-renal programs, where patients may move between statuses for very short periods. This could reduce allocation efficiency. Suggestions included adding a field in the OPTN Computer System to document when patients were verbally notified, including the date and time, or allowing centers flexibility to determine their own method of communication, provided they have a clear policy in place. Attendees generally agreed that ensuring patients are aware of their status is critical, and that programs should use communication methods suited to the patient's literacy level and access to electronic resources. While some supported written notification as long overdue, others described it as outdated technology that, without patient acknowledgement, may not provide meaningful confirmation. Concerns were also raised that repeated letters for patients who frequently transition between active and inactive status could cause confusion. There was support for the principle that patients have a right to know their status, but attendees emphasized that the process requires further refinement with transplant programs. Some suggested that notifications could be automated through OPTN systems to reduce the burden on centers. A number of attendees supported the proposal with amendments, specifically that programs should not be required to send letters. For thoracic programs with many hospitalized patients whose statuses change frequently, letters were described as impractical and burdensome. Attendees concluded that documentation of discussions through phone, in-person visits, or electronic health records should be considered sufficient.

#### **Establish Comprehensive Multi-Organ Allocation Policy**

# Ad Hoc Multi-Organ Transplantation Committee

Sentiment: 5 strongly support, 4 support, 3 neutral/abstain, 1 oppose, 1 strongly oppose Comments: Several attendees emphasized that at least one kidney from each low KDPI donor should primarily go to a kidney-alone or kidney-pancreas candidate, noting that simultaneous pancreas-kidney (SPK) recipients are fundamentally part of the kidney transplant population. Concerns were raised that placing the highest quality kidneys into multi-organ recipients—where grafts fail more frequently could reduce access for kidney-alone candidates who might derive the most long-term benefit. This was linked to a higher rate of primary non-function in kidney grafts for multi-organ groups, which could drive earlier graft failure and increased need for repeat transplants. Attendees noted the importance of monitoring pancreas utilization closely, given ongoing challenges and high non-use rates. Specific concerns were expressed about highly sensitized SPK candidates potentially losing access to SPK transplants under the proposed allocation tables, with requests that the pancreas follow the kidney in such cases, or that allocation tables prioritize high CPRA, 0-mismatch, pediatric, and prior living donor candidates for kidney-alone first, followed by SPK, and then other multi-organ candidates. Several emphasized the need to review the CPRA point scale in light of the new 250 nautical mile allocation circles, as the current system was designed before this change and may no longer reflect the appropriate balance between highly sensitized and unsensitized candidates. While some attendees affirmed that multi-organ recipients need continued access, others stressed the need for clear, uniform national guidance so that OPOs are not making inconsistent decisions. Attendees noted that allocation is already highly complex in multi-visceral cases involving heart and lungs, and adding kidney-pancreas or other combinations will increase this complexity. They recommended programming algorithms into the OPTN Computer System to reduce opportunities for error or deviation. Equity concerns were also raised, particularly by a rural transplant program that noted its kidney candidates already face systemic barriers to access, making clarity and fairness in allocation policy especially important. Several attendees agreed that the policy title should be revised to reflect the scope of the changes, and that future policy



adjustments will be necessary once data are available to evaluate outcomes. A final point highlighted the need for improved system knowledge and functionality around how allocation proceeds when a multi-organ candidate appears on a match run, as the current system does not adequately support this.

# **Updates**

# **Councillor Update**

• Comments: None

#### **OPTN Patient Affairs Committee Update**

• Comments: None

#### **OPTN Executive Update**

 Comments: Attendees raised several questions and suggestions related to patient engagement, system modernization, and data transparency. There was interest in restarting the Patient and Donor Affairs (P&DA) group, which had previously brought together patient and donor affairs leaders. The response noted that while there is currently a Patient Affairs Committee (PAC) and patient representatives serving on other committees, several Board members have also expressed interest in reviving the P&DA group, and efforts will be made to determine how best to make it effective if reestablished. Improving donor-recipient matching tools and modernizing the OPTN Computer System was highlighted as a priority. Attendees described the large number of workarounds currently in use and stressed the need for a more holistic, dynamic, and futureproof system. The response emphasized that recent discovery contracts have just been completed and that HRSA's upcoming statements of work and task orders will guide how modernization proceeds. Attendees urged careful planning to avoid building systems that will quickly become outdated. Concerns were also raised about Allocation Out of Sequence (AOOS), with some pointing out that it is fundamentally tied to the current limitations of the OPTN Computer System. Attendees noted that improving the OPTN Computer System could enable more timely and efficient allocation, though the response cautioned that if certain issues cannot be fixed within the platform, those limitations will need to be factored into how the data is interpreted and used. Several attendees emphasized the importance of improving communication channels and creating better opportunities for patients to provide feedback. Others noted that the current granularity of available data limits the ability to fully analyze system performance and suggested that greater data precision could improve efficiency and transparency. Finally, an attendee requested that the OPTN website include a list of current contractors along with their project deliverables for the coming year.

#### **HRSA OPTN Modernization Update**

• **Comments**: Attendees provided feedback to HRSA's Division of Transplantation during this session.