

Thank you to everyone who attended the Region 1 Winter 2025 meeting. Your participation is critical to the OPTN policy development process.

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

Public comment closes March 19th! Submit your comments

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

Clarify Requirements for Reporting a Potential Disease Transmission

Disease Transmission Advisory Committee

Sentiment: 3 strongly support, 5 support, 1 neutral/abstain, 0 oppose, 0 strongly oppose **Comments:** Overall, the Region supported the proposal. Concerns were raised during the meeting regarding the use of broad terminology such as "sick" and "non-sick" in relation to disease transmission, as this may cause confusion within the community, and more specific definitions were suggested. Additionally, there was a discussion about cross-clamp time during Normothermic Regional Perfusion (NRP) procedures, with a recommendation for the committee to define "cross-clamp time" in cases where multiple instances occur.

Escalation of Status for Time on Left Ventricular Assist Device

Heart Committee

Sentiment: 2 strongly support, 5 support, 1 neutral/abstain, 0 oppose, 0 strongly oppose

Comments: No Comments

Modify Lung Donor Data Collection

Lung Committee

Sentiment: 2 strongly support, 2 support, 4 neutral/abstain, 0 oppose, 0 strongly oppose **Comments**: There was support for the proposal, considering the rising use of vaping and marijuana. It was recommended that the committee adopt the standardized and objective term "cannabis" rather than "marijuana." Additionally, it was noted that Organ Procurement Organizations (OPOs) already have the necessary information, so reporting should not be burdensome. However, the implementation timeline should allow enough time for vendors and OPOs to program these fields, ensuring that OPOs do not have to document the information in two places while the programming is being completed.

Establish Comprehensive Multi-Organ Allocation Policy

Ad Hoc Multi-Organ Transplantation Committee

Comments: There is support for not including high KDPI kidneys in this allocation plan, as they are typically not used in multi-organ transplants. There is also interest in how multi-organ transplants will be managed under continuous distribution. It was recommended that flags be visible for matches involving multi-organ pairs (e.g., liver-kidney or heart-kidney), so that transplant teams know when they are not the primary recipient for certain organs. This would clarify priorities as the organs approach the operating room. An attendee recommended the committee consider the long wait times experienced by pediatric multivisceral candidates when developing the allocation prioritization.



Barriers Related to the Evaluation and Follow-Up of International Living Donors

Ad Hoc International Relations Committee

Sentiment: 5 strongly support, 2 support, 0 neutral/abstain, 0 oppose, 0 strongly oppose **Comments:** This was not discussed during the meeting, but attendees were able to submit comments. The document effectively highlights key challenges and offers practical strategies to enhance donor safety and ethical oversight. Additional challenges include visa and immigration hurdles, with a suggestion to streamline guidance on visa processes, and psychosocial support, as donors may experience stress related to travel, separation, and cultural differences. Recommended additional strategies include fostering international partnerships with hospitals in donor home countries for improved evaluation and follow-up, as well as using remote ILDA and SW assessments, such as virtual interviews, to assess voluntariness and identify potential stressors before travel.

Monitor Ongoing eGFR Modification Policy Requirements

Minority Affairs Committee

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

Comments: No comments.

Updates to National Liver Review Board Guidance and Further Alignment with LI-RADS

Liver & Intestinal Organ Transplantation Committee

Sentiment: 3 strongly support, 3 support, 1 neutral/abstain, 0 oppose, 0 strongly oppose Comments: This was not discussed during the meeting, but attendees were able to submit comments. A member expressed strong support for updating this policy to include contrast-enhanced ultrasound (CEUS) as an imaging modality for HCC diagnosis. A member shared support for the proposed updates, along with several recommendations for improvements. The references provided by the committee support acceptable post-transplant survival for patients with vascular invasion and extrahepatic tumor, but the member disagrees with these limitations to exception point access. They do not find it useful to include a negative staging laparotomy at the time of transplant as a criterion for exception points. The member supports broadening access to exception points for patients with sclerosing cholangitis and requests clarification from the committee regarding what qualifies as a history of resistant organisms, specifically whether infection history is required, as opposed to mere colonization.

Continuous Distribution Updates

Continuous Distribution of Kidneys, Winter 2025

Kidney Transplantation Committee

Comments: This was not discussed during the meeting, but attendees were able to submit comments. An attendee stated the importance of the committee addressing non-use and the factors that lead to out-of-sequence allocation should be a key component of the work to establish kidney continuous distribution. A comment was made in support of the committee's work, saying that it is important that the OPTN modernization efforts should not slow down the progress of this important project. A member shared concern that broader sharing of organs has resulted in an increase in non-use, with allocation taking too much time, especially medically complex kidneys. The member requests that any additional complexity be accompanied by efforts to increase efficiency and consequences for those that use a provisional yes when they have not actually evaluated the offer. One comment expressed skepticism



that continuous distribution would measurably improve the system due to the additional complications that would come with it.

Continuous Distribution of Pancreata, Winter 2025

Pancreas Transplantation Committee

Comments: This was not discussed during the meeting, but attendees were able to submit comments. An attendee strongly supports moving forward with continuous distribution and agrees with the new criterion for medical urgency but raised concerns regarding a significant lack of efficiency in pancreas and kidney/pancreas allocation, with a suggestion that pancreas continuous distribution focus on improving efficiency and establishing more realistic donor criteria. Another comment emphasized prioritizing local allocation first, as time is critical for pancreas transplantation. On member shared that pancreas transplantation is seen as a primarily local-regional treatment, and there is significant variation across regions in the utilization of this therapy for diabetes management. In some regions, like Region 1, pancreas transplantation is rarely used, and expanding the allocation process broadly could unnecessarily complicate the system without offering significant benefits.

Updates

Councillor Update

• Comments: None

OPTN Patient Affairs Committee Update

• Comments: None

OPTN Update

• Comments: There was a discussion regarding how INVEST will align with the Board of Directors (BOD) if the BOD does not have authority over the Transitional Nominating Committee and special election process, as well as a request for the designation agreement to be made public. The critical comment related to normothermic regional perfusion (NRP) was discussed. A member shared that in Region 1, NRP has increased transplants and is mainly used for abdominal NRP, facilitated by the OPO, and expressed concern about the time and energy required to meet HRSA's request. The member noted that there is no mention of transplant center protocols in the request.

MPSC Update

• **Comments**: A member shared appreciation for the opportunity to serve on the MPSC. An attendee expressed confusion around how associate councillor positions will be handled with the upcoming OPTN Board of Directors election.

Feedback Session on OPTN Modernization

Attendees provided feedback to HRSA's Division of Transplantation during this session.