

## **OPTN Policy Oversight Committee**

### **Meeting Summary**

**March 13, 2025**

### **Teleconference**

**Jennifer Prinz, BSN, MPH, Chair**

**Erika Lease, MD, Vice Chair**

## **Introduction**

The OPTN Policy Oversight Committee (“POC” or “the Committee”) met via teleconference on 03/13/2025 to discuss the following agenda item:

1. Welcome and updates
2. New Project Review: *2025 Histocompatibility HLA Table Update*
3. New Project Review: *Develop Lung Review Board Educational Narrative Examples*
4. Public Comment Review: *Revisions to Human Immunodeficiency Virus (HIV) Policies to Align with Federal Regulatory Updates*

The following is a summary of the Committee’s discussions.

### **1. Welcome and updates**

The Committee discussed feedback received from the OPTN Executive Committee regarding the February 2025 proposals sent for approval. The policy project sponsored by the Pediatric committee was approved. The guidance document project sponsored by the Pancreas committee was not approved and the Executive Committee recommended the Pancreas committee revise and adjust their approach, assessing whether a policy option might be appropriate. The policy project sponsored by the Kidney committee was not approved as a standalone project. The Executive Committee advised that this project be incorporated into the Allocation Out of Sequence (AOOS) directive project plan.

#### Summary of discussion:

A member inquired why the Committee moved forward with recommending approval of the pancreas guidance document project, given that the OPTN has been shifting away from issuing guidance documents in favor of more actionable policy approaches. The Chair explained that this project stemmed from recent work by the American Society of Transplant Surgeons (ASTS), and the document would aim to enhance training, raise awareness, and improve pancreas transplantation and procurement practices. However, the Executive Committee provided feedback suggesting that OPTN’s role in this area might be better served through policy development rather than a guidance document.

Another member asked whether additional feedback was provided on the Executive Committee’s recommendation to wait for the AOOS directive before proceeding with the Kidney project, which seeks to develop an expedited placement proposal. The Chair clarified that the Executive Committee’s rationale was that ongoing efforts were already underway in this area due to the AOOS directive. Rather than pausing the Kidney project, the recommendation was to integrate it into the broader project plan.

## 2. New Project Review: 2025 Histocompatibility HLA Table Update

The Committee reviewed the following project: *2025 Histocompatibility HLA Table Update*.

### Summary of discussion:

Does the Committee recommend approval of the new project to the Executive Committee?

Votes: 13 yes, 1 no, 0 abstain

A member asked whether patient safety is considered in the current benefit scoring metrics. OPTN Contractor staff clarified that patient safety is not explicitly factored into benefit scoring unless it aligns with a strategic plan goal. The Chair noted that while patient safety has historically been included under strategic priorities, it should remain a distinct focus moving forward. Another member suggested that patient safety be treated as a standalone category rather than being grouped under population impact, emphasizing its fundamental importance.

One member questioned why such patient safety-related projects, including this one, could not be implemented more quickly given their critical nature. Another member highlighted the risks associated with delays, particularly in HLA typing and antigen listings, which could impact offer screening and patient outcomes. The Vice Chair outlined the challenges a similar project had faced, citing extensive procedural requirements such as mandatory public comment periods, board approvals, and policy revisions. They also noted that past attempts to expedite patient safety initiatives had encountered procedural hurdles and resistance from stakeholders who prioritized procedural compliance over urgent implementation.

Recognizing the urgency of these concerns, a member proposed a motion for the Committee to support an expedited approval pathway for this project. The motion was seconded by two other members. Staff clarified that while any changes to OPTN policy would still require a public comment period, there is precedent for an abbreviated process in certain cases. Staff also clarified the project timeline as proposed already includes an expedited implementation pathway after public comment, barring any significant concerns raised during public comment.

Based on the project information provided compared to the benefit score components, the project was assigned a benefit score of 91. POC members confirmed the benefit score for the project.

The Committee then voted on advancing the project to the OPTN Executive Committee for approval and supporting an expedited approval pathway. The outcome was 13 in favor, 1 opposed, 0 abstaining.

### Next steps:

The Committee's recommendation will be communicated to the Executive Committee. The project will be reviewed by the Executive Committee for approval.

## 3. New Project Review: Develop Lung Review Board Educational Narrative Examples

The Committee reviewed the following project: *Develop Lung Review Board Educational Narrative Examples*.

### Summary of Discussion:

Does the Committee recommend approval of the new project to the Executive Committee?

Votes: 14 yes, 0 no, 0 abstain

One member expressed concerns about the lack of measurability in the identified key metric as it's based on consistency in narratives, noting that review board decisions are often made on a case-by-case basis with a qualitative approach. This results in an inherently subjective system where different centers submit vastly distinct levels of detail in their requests. They questioned whether it would be possible to introduce a more structured mechanism, such as rubric, to help standardize the evaluation process and improve consistency across applications. Additionally, they raised doubts about whether providing eight to ten examples of well-prepared requests would be truly effective, given the wide variation in patient cases and clinical circumstances. They pointed out that in other medical processes, it is difficult to provide enough examples to account for every scenario, making standardization particularly challenging.

The Lung Committee Vice Chair acknowledged these concerns and explained that while exception requests are inherently individualized, providing structured examples could introduce a level of standardization. The current approach has shown that some centers are more adept at crafting strong requests while others struggle, and to counter this variability, providing examples can level the playing field and ensure patients are given the best chance at receiving fair consideration for the priority request.

Another member, drawing from their experience in pediatric transplant review boards, reinforced the need for more structure. They noted that similar issues exist in pediatric exception requests, where providers are asked to submit a short narrative but often fail to include critical information. As a result, reviewers are sometimes left with incomplete or ambiguous cases, making fair decision-making difficult. They strongly supported the idea of providing structured examples but questioned whether this approach would be sufficient. They asked whether the goal was simply to provide case examples for educational purposes or if a more structured template could be incorporated directly into the request submission process.

The Lung Vice Chair responded that while training materials, including case examples, would be made available, there were no current plans to implement a formal template within the request system itself. The idea is to guide centers by showing well-prepared examples rather than imposing a standardized form. The member pointed out that in other review processes, even when clear guidance is provided, many centers still submit poorly structured or incomplete requests. They suggested that as the organ allocation system continues to modernize, there should be a long-term goal of developing more structured request formats across all organ types.

Other members offered their agreement that this project and future efforts should explore ways to further standardize the exception request process across all organ groups.

Based on the project information provided compared to the benefit score components, the project was assigned a benefit score of 14. POC members confirmed the benefit score for the project. Members voted on sending the project to the OPTN Executive Committee for approval, 14 voted yes, 0 no, 0 abstain.

### Next Steps:

The project will be reviewed by the Executive Committee for approval.

#### **4. Public Comment Review: Revisions to Human Immunodeficiency Virus (HIV) Policies to Align with Federal Regulatory Updates**

The Committee reviewed the following project: *Revisions to Human Immunodeficiency Virus (HIV) Policies to Align with Federal Regulatory Updates*.

##### Summary of Discussion:

Does the Committee recommend approval of the new project to the Executive Committee?

Votes: 14 yes, 0 no, 0 abstain

Members agreed that this project is timely and should be moved forward for special public comment. Based on the project information provided compared to the benefit score components, the project was assigned a benefit score of 91. POC members confirmed the benefit score for the project. Members voted on sending the project to the OPTN Executive Committee for approval, 14 voted yes, 0 no, 0 abstain.

##### Next Steps:

The project will be reviewed by the Executive Committee for approval.

##### **Upcoming Meeting(s)**

- April 10, 2025 - Teleconference

## Attendance

- **Committee Members**
  - Aneesha Shetty
  - Cynthia Forland
  - Dennis Lyu
  - Erika Lease
  - Heather Bastardi
  - Jennifer Prinz
  - Jason Huff
  - Neha Bansal
  - Lisa McElroy
  - Lisa Stocks
  - Lorrinda Gray-Davis
  - Ty Dunn
  - Steven Potter
  - Oscar Serrano
  - Rachel Miller
  - Kelley Hitchman
- **SRTR Representatives**
  - Allyson Hart
  - Jon Snyder
- **HRSA Representatives**
  - Steve Keenan
- **UNOS Staff**
  - Lindsay Larkin
  - Kaitlin Swanner
  - Susan Tlusty
  - Cole Fox
  - Laura Schmitt
  - Matt Cafarella
  - Stryker-Ann Vosteen
  - Jamie Panko
  - Kelley Poff
  - Samantha Noreen