# OPTN Ad Hoc Disease Transmission Advisory Committee (Open & Closed Session)
# Meeting Summary
# April 28, 2025
# Conference Call

**Stephanie Pouch, MD, MS, Chair**
**Rachel Miller, MD, Vice Chair**

## Introduction

The OPTN Ad Hoc Disease Transmission Advisory Committee (the Committee) met via WebEx teleconference on 04/28/2025 to discuss the following agenda items:

1. Public Comment Feedback Overview: *Revisions to Human Immunodeficiency Virus (HIV) to Align with Federal Regulatory Updates*
2. Closed Session

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

## 1. Public Comment Feedback Overview: *Revisions to Human Immunodeficiency Virus (HIV) to Align with Federal Regulatory Updates*

The Committee received an overview of public comment feedback on *Revisions to Human Immunodeficiency Virus (HIV) to align with Federal Regulatory Updates*. The proposal was open for public comment from March 21 to April 22, 2025. Feedback requested included the following:

- Whether the community considers that the additional safety requirements being proposed are:
  - Adequate and or appropriate, or
  - Insufficient- additional patient safety measures should be considered, or
  - Unnecessary and resource-intensive
- Any questions about implementation, logistics, or training that can be addressed prior to implementation.

he Committee also received a comment from the American Society of Transplantation (AST), which expressed overall support for the proposal but raised specific concerns regarding the removal of clinical research criteria and HOPE Act variance participation requirements for living kidney and liver transplants involving both HIV-positive donors and recipients. AST emphasized the limited data available on living donors with HIV and highlighted the need for more robust information on long-term outcomes for this population. They noted that the number of living donor transplants performed under the HOPE Act remains relatively small, and more comprehensive data is needed to understand potential risks. AST stressed the importance of ensuring that donors are thoroughly informed about the implications of their decision to donate because informed consent with living donors living with HIV is critical.

Similarly, the Living Donor Committee (LDC) echoed these concerns in a memo to the Committee. They recommended that informed consent processes for HIV-positive living donors explicitly include disclosure of the current data limitations. Additionally, the LDC suggested collaborating with the Scientific Registry of Transplant Recipients (SRTR) to monitor and collect data on this donor population, suggesting that long-term outcomes are tracked and analyzed to provide valuable insight into the safety and efficacy of the policy.

The Committee was asked the following questions:

- Does the Committee have feedback on the living donor memo and AST comment?
- Are there other thoughts on the community feedback?

Data summary:

Public comment themes identified:

- Strong support for both the alignment with federal rules and additional patient safety measures.
- Feedback expressed concerns about the burden of patient safety.

Summary of discussion:

**Decision #1:** The Committee endorsed the Living Donor Committee's recommendation to collaborate with SRTR on the long-term monitoring of outcomes for living donors with HIV.

**Decision #2:** The Committee concluded that no changes to the proposal were warranted based on the public comment feedback.

The Chair expressed appreciation for the public comments received and emphasized the importance of the transplant community having a vested interest in ensuring positive outcomes for all living donors. She noted that historically, data collection for living donors has been limited. However, based on recommendations from the LDC, this presents an opportunity to enhance monitoring of living donor outcomes, including those of individuals living with HIV. She stressed the importance of the committee having the capability to collect long-term data on this population.

Another member agreed, highlighting the need for data collection efforts to be both timely and feasible. She explained that while there is often a desire to gather meaningful data, the necessary systems to support such efforts may not yet exist. The member further emphasized that transplant programs should be actively monitoring their donors for complications and side effects, and ensuring that donors are properly consented. This includes helping donors understand their individualized risks. Not all individuals living with HIV will face the same long-term risks, as these may be influenced by other coexisting medical conditions. Therefore, it is essential that living donors receive appropriate and comprehensive informed consent.

Staff noted that the LDC is currently developing a project aimed at collecting data on living donor candidates. The goal is to gather baseline information on individuals before donation, including those who begin the evaluation process but ultimately do not proceed with donation, to serve as a comparator group. The project is designed to transition data collection responsibilities one year post-transplant to the SRTR, which is working to expand its Living Donor Collective and support long-term follow-up of living donors.

A member commented on the uncertainty surrounding the project, noting that since it is still under development, it is difficult to predict what data will ultimately be collected. She expressed concern about relying on a system that is not yet fully defined. Nonetheless, she agreed that individuals living with HIV may face additional risks and should be closely monitored after making an informed decision about whether to proceed with donation.

Another member inquired about the number of kidney transplants performed from HIV-positive living donors since the implementation of the HOPE Act. The Chair replied roughly three transplants have taken place.

The Committee agreed on the importance of long-term monitoring of outcomes for living donors with HIV. They supported efforts to capture these outcomes in collaboration with the SRTR and the ongoing work of the LDC. However, no changes to the proposal were recommended based on the public comment feedback.

The Committee's feedback will be summarized and incorporated into the briefing paper, reflecting consensus on the need for more long-term outcome data, the importance of comprehensive informed consent for living donors, and the value of educational efforts to support robust consent processes.

Next steps:

The Committee will vote on the final proposal and policy language at an upcoming meeting, with the goal of submitting it to the OPTN Board of Directors for consideration in June 2025.

**2. Closed Session**

The Committee had a closed session review of potential donor-derived transmission events.

**Upcoming Meeting**

- May 6, 2025

**Attendance**

- **Committee Members**
  - Lara Danziger-Isakov
  - Stephanie Pouch
  - Rachel Miller
  - Shirish Huprikar
  - Maheen Abidi
  - Cindy Fisher
  - Gabriel Maine
  - Dong Lee
  - Marty Sellers
  - Pooja Singh
  - Jas Kaur
  - Gerald Berry
  - Helen Te
  - Tanvi Sharma
- **HRSA Representatives**
  - Irma Sison
- **CDC Representatives**
  - Pallavi Annambhotla
  - Sridhar Basavaraju
  - Kelsey McDavid
- **FDA Representatives**
  - Hanh Khuu
- **UNOS Staff**
  - Tamika Watkins
  - Cole Fox
  - Logan Saxer
  - Dzhuliyana Handarova
  - Houlder Hudgins
  - Joel Newman
- **Other Attendees**