

Meeting Summary

OPTN Ad Hoc Disease Transmission Advisory Committee Meeting Summary May 6, 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 05/06/2025 to discuss the following agenda items:

- 1. Update: Rabies Directive
- 2. Review Policy Language & Vote: Revisions to Human Immunodeficiency Virus (HIV) to Align with Federal Regulatory Updates
- 3. Review Policy Language & Vote: Requirements for Reporting a Potential Disease Transmission

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

1. Update: Rabies Directive

In April 2025, Health Resources and Services Administration (HRSA) tasked the Committee with recommending updates to OPTN Policy to help reduce the risk of donor-derived rabies transmission. As part of this directive, Organ Procurement Organizations (OPOs) will collect relevant data to inform potential policy changes. Once gathered, the data will be reviewed by DTAC leadership, the Centers for Disease Control and Prevention (CDC), and HRSA. The Committee will also collaborate with other OPTN Committees—including the Patient Affairs, Transplant Coordinator, and OPO Committees—to gather additional input on next steps to reduce the risk of donor-derived rabies infection. Completion of the directive is targeted for July 2, 2025, pending receipt of the necessary data from HRSA.

2. Review Policy Language & Vote: Revisions to Human Immunodeficiency Virus (HIV) to Align with Federal Regulatory Updates

The Committee reviewed the proposed policy language and voted on the revisions to the Human Immunodeficiency Virus (HIV) policy to align with recent federal regulatory updates. During the April 28th Committee meeting, public comment feedback was presented, including input from the American Society of Transplantation (AST) and the Living Donor Committee. These comments focused on living donor safety and the relatively small number of living donors with HIV who have undergone transplantation.

A potential policy change was proposed to revise the confirmed consent process for individuals living with HIV who wish to become living donors. Specifically, it was recommended that the policy be updated to require disclosure to all kidney and liver living donors with HIV about the potential health impacts and long-term outcomes associated with donation. This proposed update aligns with feedback from the Living Donor Committee, which emphasized the importance of ensuring that donors are fully informed.

Summary of Discussion:

Decision #1: There was consensus to adopt the advised policy language.

The Committee reviewed the non-substantive changes made to the policy language. Members agreed that the additions appropriately support the disclosure requirements for living donor consent. Additionally, all mentions of the NIH final rule were updated to reflect the correct terminology: "NIH final notice."

Does it support the proposed policy language as revised?

Vote: Support: 13 Abstain: 0 Oppose:0

Next steps:

The Revisions to Human Immunodeficiency Virus (HIV) to Align with Federal Regulatory will be presented for approval at the June 2025 OPTN Board meeting.

3. Review Policy Language & Vote: Requirements for Reporting a Potential Disease Transmission

The Committee reviewed and voted on the policy language for Requirements for Reporting a Potential Disease Transmission, as well as the supporting documents for this project, including the educational material, which is an FAQ document and the Pathogens of Special Interest list. The policy language included structural and clarification changes.

Summary of Discussion:

There were no further discussions.

Next steps:

The Requirements for Reporting a Potential Disease Transmission will be presented for approval at the June 2025 OPTN Board meeting.

Upcoming Meeting

• May 23, 2025

Attendance

Committee Members

- Stephanie Pouch
- Marty Sellers
- Riki Graves
- o Helen Te
- o Gabriel Maine
- o Gerald Berry
- o Anna Hughart
- o Fernanda Silveria
- o Pooja Singh
- o Cindy Fisher
- o Tanvi Sharma
- o Oyedele Adeyi
- Lara Danziger-Isakov
- o Lorenzo Zaffiri

• HRSA Representatives

CDC Representatives

- o Kelsey McDavid
- Sridhar Basavaraju
- o lan Kracalik

FDA Representatives

- o Hanh Khuu
- o Irma Sison

UNOS Staff

- o Tamika Watkins
- o Cole Fox
- o Sandy Bartal
- o Lloyd Board
- o Bonnie Felice
- o Houlder Hudgins
- o Logan Saxer
- o Dzhuliyana Handarova
- o Kim Manley

Other Attendees