

**OPTN Ethics Committee
Meeting Summary
June 26, 2025
WebEx Meeting**

**Andrew Flescher, PhD, Chair
Sanjay Kulkarni, MD, Vice Chair**

Introduction

The Ethics Committee (“Committee”) met via WebEx teleconference on 6/26/2025 to discuss the following agenda items:

1. Welcome and Announcements
2. Group 2 Discussion: Ethical Analysis of Possible Impacts Xenotransplantation on Human Allograft Organ Allocation

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

1. Welcome and Announcements

Upcoming meetings are scheduled for July 17 and August 21. The Vice Chair will lead the August session.

The Out-of-Sequence Allocation (AOOS) Paper was submitted to the *American Journal of Transplantation* and is under review. The committee successfully condensed the paper from 17,000 to 3,000 words while preserving its nuance and impact.

A new Donor After Cardiac Death (DCD) Directive Workgroup, led by the Organ Procurement Organizations (OPO) Committee, is developing policy guidance for family information during DCD organ procurement. The Ethics Chair will represent the Ethics Committee, with potential delegation to other members.

The Chair noted a broader shift in the committee’s role: from independently selecting projects to engaging in more collaborative, policy-driven initiatives due to tighter budgets and evolving organizational priorities

AOOS Directive Workgroup Update: Two committee members provided a comprehensive update on their participation in this OPTN Executive Committee workgroup:

The operational definition of AOS was expanded to include not only transplants but also offers and acceptances that deviate from the match run and OPTN policy.

The analytic definition is constrained by available data, relying on specific bypass codes to identify AOS events. The group debated the limitations of these codes and discussed the potential for AI and sentiment analysis to extract insights from free-text fields.

One workgroup member emphasized the need to capture attempted offers, not just completed transplants, to fully understand AOS patterns.

The Ethics Chair noted that this work reflects the Committee's growing influence in shaping national policy.

2. Group 2 Discussion: Ethical Analysis of Possible Impacts of Xenotransplantation on Human Allograft Organ Allocation

A committee member led the presentation for Group 2, focusing on the question: how should the system treat patients who receive a xenotransplant in relation to the allograft waitlist?

Framing the Ethical Dilemma

The group considered three options:

1. Allow patients to remain on the waitlist in an inactive status.
2. Permanently remove them from the waitlist.
3. Delist them upon xenotransplantation but allow re-listing if the xenograft fails.

Group Two recommended the third option. Their rationale was grounded in fairness and consistency with existing allograft policies. Allowing patients to remain on the list while benefiting from a functioning xenograft could create an unfair dual advantage. Conversely, permanently removing them would be unjust, especially if the xenograft fails or provides no benefit.

Ethical Principles and Precedents

The group's reasoning drew on several ethical principles:

- Fairness to all patients: The system must avoid giving xenograft recipients an undue advantage over others on the waitlist.
- Protection from harm: Patients should not be penalized for participating in experimental treatments.
- Autonomy: Patients should not be coerced into choosing between a xenograft and their place on the waitlist.
- Consistency: The policy should align with how allograft recipients are treated—delisted upon transplant, with the possibility of re-listing if the graft fails.

A member emphasized that the recommendation to delist was not punitive but a mechanism to prevent inequity. He also noted that re-listing should restore previously accrued wait time and potentially include additional priority, especially if the xenograft fails quickly.

Summary of Discussion:

A member expressed concern about assuming equivalence between xenografts and allografts, especially given the experimental nature of xenotransplantation. She cautioned against delisting patients based on an unproven therapy.

Another member proposed a “safety net” model, similar to existing policies for early graft failure in kidney and liver transplants. He suggested defining a minimum success period—such as one year—before delisting a patient.

There were questions raised about how xenograft success should be measured and whether the burdens (e.g., immunosuppression, side effects) are comparable to allografts. How quickly can patients be re-listed if needed?

It was clarified that current policy requires delisting after allograft transplant and suggested applying the same standard to xenografts for consistency. It was acknowledged, however, that re-listing logistics and clinical eligibility would need to be addressed.

Urgent re-listing pathways exist for liver and heart transplants but not for kidney. It was recommended that similar mechanisms for kidney xenograft failures be developed.

Operational and Policy Considerations

The group rejected the idea of keeping patients in an inactive status, as this would allow them to accrue wait time while benefiting from a functioning xenograft—an outcome deemed unfair. Instead, they proposed delisting with the option to re-list if the xenograft fails, restoring prior wait time and potentially granting additional priority.

They also discussed the limitations of current re-listing processes and the need for policy updates to ensure timely re-evaluation and reactivation, especially for kidney recipients.

Concluding Reflections

The Chair noted that Group 2 offered clear, actionable guidance—a shift from the Committee’s traditional approach of raising questions rather than providing firm recommendations. He acknowledged that while this approach may foreclose some options, it responds to the community’s growing demand for clarity and direction.

The Committee agreed that further discussion is needed, particularly to refine definitions of xenograft success and failure, and to ensure that re-listing mechanisms are equitable and efficient. Options for a follow-up meeting to continue the conversation and incorporate broader feedback will be discussed and communicated to the Committee by staff.

Upcoming Meeting(s)

- July 17, 2025

Attendance

- **Committee Members**
 - Andy Flescher
 - Joel Wu
 - Gloria Chen
 - Lois Shepard
 - Laura Jokimaki
 - Felicia Wells-Williams
 - Megan Urbanski
 - Jennifer Dillon
 - Fisayo Adebisi
 - Sena Wilson Sheehan
 - Matthew Wilkinson
 - Laura McCowan
 - Grace Lee-Riddle

- **HRSA Representatives**
 - None
- **SRTR Staff**
 - Bryn Thompson
- **UNOS Staff**
 - Cole Fox
 - Emily Ward
 - Ross Walton
 - Lindsay Larkin
 - Laura Schmitt
 - Kaitlin Swanner