OPTN Ethics Committee
Meeting Summary
July 17, 2025
WebEx Meeting

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

Introduction

The Ethics Committee ("Committee") met via WebEx teleconference on 7/17/2025 to discuss the following agenda items:

1. Welcome and Announcements
2. Group 2 Discussion (Continued): 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 schedule for August 21st and September 18th. The Vice Chair will lead the August session.

The Chair provided several key updates. He noted that the next full committee meeting would be held on August 21, which he would miss due to international travel. The Vice Chair will lead that session. Leadership submitted the introduction for the committee's current ethics project / white paper on xenotransplantation, and it was now with staff for review.

A major topic was the rejection of the committee's Allocating Organs Out-of-Sequence Allocation (AOOS) paper by the American Journal of Transplantation. The Chair expressed disappointment, noting that one reviewer believed AOOS resolved the non-use)or organs) problem and criticized the paper for lacking a utility-focused approach. Despite this, the paper was reformatted, incorporated feedback, and submitted it to Current Transplantation Reports, which agreed to expedite review.

Staff shared updates on four HHS/HERSA directives:
1. Normothermic Regional Perfusion (NRP) – Awaiting final direction.
2. Donation After Cardiac Death (DCD) – Policy development underway.
3. Rabies Transmission – Addressed by the Disease Transmission Advisory Committee.
4. Allocating Organs Out-of-Sequence (AOOS) – Two Ethics members were appointed to represent the Ethics Committee.

The Chair emphasized that the Ethics Committee is increasingly involved in interdisciplinary policy work, a shift from its traditional role of ethical analysis. Staff noted that these new directives reflect a broader evolution in the committee's responsibilities.

Additional updates included the start of a new OPTN Board of Directors on July 1, and a resolution passed by the previous board to pause non-critical committee work for Q4 FY2025. This affects the Transplant Administrators, Vascularized Composite Allograft, and International Relations committees.

The Chair raised concerns about the centralization of project selection, suggesting that committee autonomy may be diminishing. While staff could not speak on behalf of Health Resources and Services Administration (HRSA) or the OPTN Board, they encouraged members to observe the upcoming board meeting for more insight.

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

Summary of Discussion:

The second half of the meeting focused on the Committee's ongoing work on the Xenotransplantation (Xeno) white paper. The Chair introduced the discussion by highlighting a key tension: Group 1 emphasized the current impracticality of Xeno as a viable therapy, while Group 2 argued that ethical frameworks must be in place in anticipation of future viability. The Chair framed this as a necessary reconciliation between empirical reality and ethical preparedness.

The Group 2 lead committee member outlined shared ethical commitments:
- Participants in Xeno trials should not be worse off for having participated.
- Patients must be able to make meaningful, informed choices.
- Xeno is not currently equivalent to allografts, but future benefits are possible.

The central question was: What should happen to a patient's waitlist status after receiving a Xeno transplant as part of a clinical trial? The Group 2 lead presented three potential approaches:
1. Keep the patient active on the waitlist.
2. Make the patient inactive.
3. Delist and re-list the patient based on medical need.

Group 2 favored using existing policies rather than creating a new, special pathway. The Lead emphasized that any changes to listing status should be based on medical need, not trial participation alone.

The Group 1 Lead agreed that eligibility for clinical trials and transplant waitlists should be treated as parallel and independent processes. Group 1 had focused on initial listing criteria and had not addressed post-transplant status, assuming Group 2 would take that on.

A member raised a practical concern: if a patient qualifies for both a clinical trial and the allograft waitlist, what happens after they receive a Xenotransplant? Should they remain listed, be deactivated, or be delisted entirely?

The Vice Chair added that clinical trial design typically requires participants to be inactive on other treatment lists to preserve the integrity of trial endpoints. He noted that existing mechanisms—such as marking a patient "too well for transplant"—could be used without creating a new system.

Another member brought in a research ethics perspective, emphasizing that participants have the right to withdraw from trials at any time. She questioned whether current medical need criteria are sufficient, given the uncertainty surrounding Xeno outcomes. The Group 2 Lead responded that Group 2's position was to rely on existing listing and re-listing standards, which are based on medical need regardless of the preceding treatment.

The group also discussed the risk of "double dipping"—where a patient might benefit from both a Xeno transplant and an allograft in a way that could be seen as unfair. Two members discussed that this

concern is mitigated by the fact that Xeno currently offers no clear benefit and that existing policies already accommodate primary graft failures.

A member raised a key point: there are no special pathways for patients who have undergone other non-equivalent bridge therapies. Creating one for Xeno might set a precedent that complicates the system unnecessarily.

The Vice Chair noted the conceptual challenge of treating Zeno organs as medical devices, even though they function as organs.[1] This dual identity complicates how they are ethically and clinically categorized.

A member returned to the issue of uncertainty, suggesting that the experimental nature of Xeno might justify a special pathway. She emphasized that medical need assessments might not accurately reflect the risk of Xeno graft failure, especially in the early days post-transplant.

The Group 2 Lead acknowledged this concern but reiterated that the committee's role is to recommend ethical frameworks, not clinical trial design. He emphasized that standardized processes based on medical need remain the most equitable and practical approach.

The Chair concluded the discussion by noting that the committee may need to present multiple perspectives in the final white paper, including both majority and dissenting views. He emphasized the importance of careful language—particularly verb tenses—to reflect both current limitations and future possibilities.

The meeting ended with a reminder of the next session on August 21, and the Chair encouraged members to reach out with any questions about the AOOS paper or the Xeno project.

Upcoming Meeting(s)

- August 21, 2025
- September 18, 2025

[1] While xenotransplant was referred to as a "device" during the meeting, the current xenotransplant kidney which has been approved to begin clinical trials is being reviewed by the Food and Drug Administration (FDA) through a Biologics License Pathway (BLA), not as a device.

Attendance

- **Committee Members**
  - Andy Flescher
  - Joel Wu
  - Gloria Chen
  - Lois Shepard
  - Felicia Wells-Williams
  - Megan Urbanski
  - Fisayo Adebiyi
  - Sena Wilson Sheehan
  - Matthew Wilkinson
  - Jen Dillon
  - Laura Madigan-McCown
  - Grace Lee-Riddle
  - Lisa Paolillo
  - Robert Truog
  - Sheila Bullock

- **HRSA Representatives**
  - None
- **SRTR Staff**
  - None
- **UNOS Staff**
  - Cole Fox
  - Ross Walton
  - Lindsay Larkin