

OPTN Ethics Committee

Meeting Summary

May 15, 2025

WebEx Meeting

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

Introduction

The Ethics Committee ("Committee") met via WebEx teleconference on 5/15/2025 to discuss the following agenda items:

1. Welcome and Announcements
2. Review White Paper Timeline, Logistics, and Rules of Collaboration
3. Group 1 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

Staff provided logistical updates, including the upcoming OPTN public comment period (August 8 through October 7) and the scheduling of future full committee meetings. Calendar invitations have been sent and meetings will continue on the third Thursday of each month, with exceptions for holidays.

2. Review White Paper Timeline, Logistics, and Rules of Collaboration

The Committee reviewed the project timeline for the current xenotransplantation white paper. Unlike previous papers, this one is intended to be more succinct while still comprehensive. The first draft for each group is due by September 2, 2025, and all contributions will be compiled into a shared Google document for version control. Members were reminded to use APA8 citation format and to ensure timely submission of their group's sections.

3. Group 1 Discussion: Ethical Analysis of Possible Impacts of Xenotransplantation on Human Allograft Organ Allocation

A committee member led the presentation for Group 1, focusing on the ethical implications of patient participation in xenotransplantation trials and how this can impact eligibility for the deceased donor organ waitlisting.

Key Ethical Questions and Group 1's Analysis:

1. Can patients be eligible for both xenotransplant trials and deceased donor waitlisting?
 - **Yes.** Group 1 concluded that these are distinct processes with separate eligibility criteria. Participation in one should not preclude eligibility for the other.
2. Does participation in a xenotransplant trial affect a patient's waitlist status?

- **No.** Trial participation should not automatically render a patient inactive on the transplant waitlist. Inactivation should be based solely on clinical condition.
3. Should patients be forced to choose between trial participation and waitlisting?
 - **No.** The group emphasized the importance of patient autonomy, arguing that patients should not be coerced into choosing one path over another if they meet the criteria for both.
 4. Is dual eligibility ethically problematic (i.e., “double dipping”)?
 - **Not currently.** Given that xenotransplantation is not yet equivalent to standard allografts, dual eligibility does not constitute an unfair advantage. However, this may need to be revisited if xenotransplantation becomes standard care.
 5. Can patients ineligible for deceased donor transplants participate in xenotransplant trials?
 - **Yes, conditionally.** While this may fall outside OPTN’s direct scope, the group argued that ineligibility for one pathway should not automatically disqualify a patient from the other, provided they meet the trial’s criteria.
 6. Should listing for transplant be delayed due to trial participation?
 - **No.** The group strongly opposed any delay in listing based on trial involvement. Eligibility and timing should be determined independently.
 7. Should patients who receive a xenograft be made inactive on the waitlist?
 - **Possibly.** While not the focus of Group 1, there was acknowledgment that patients receiving a xenograft might be made inactive temporarily, similar to those receiving an allograft. A grace period could be considered, especially if the xenograft fails early.

Ethical Principles Emphasized:

- **Autonomy:** Patients must retain the right to choose their treatment path.
- **Equity and Justice:** Access to trials and waitlisting should be fair and transparent.
- **Transparency:** Clear communication and policy guidance are essential.
- **Avoiding Care Gaps:** Patients should not face delays or denials due to overlapping processes.

Summary of Subsequent Committee Discussion:

Terminology and Scope Clarification:

The Vice Chair raised an important point about the use of the term “listed” in reference to xenotransplantation trials. He clarified that patients are not “listed” for trials in the same way they are for organ transplants; rather, they are deemed “eligible.” The Group 1 Lead acknowledged the distinction and agreed to revise the language accordingly in the group’s documentation.

Double Dipping and Ethical Justification:

Members addressed the concern of “double dipping”—the idea that patients might gain an unfair advantage by participating in both a clinical trial and being on the transplant waitlist. A member emphasized that since xenotransplantation is not currently equivalent to standard allografts in terms of outcomes or certainty, the two should be treated as separate and non-competing pathways. He added that as long as the eligibility criteria for each are independent and do not influence one another, dual participation is ethically justifiable.

The Committee Chair encouraged the group to explicitly address potential objections in their writing, even if only briefly, to strengthen the ethical rationale and preempt criticism. He also noted the importance of acknowledging that the ethical landscape may shift if xenotransplantation becomes standard care in the future.

Resource Allocation and System Burden:

A member raised a concern about the potential strain on resources, noting that patients undergoing evaluations for both transplant listing and trial participation may require significant institutional effort. However, she concluded that this concern likely does not outweigh the ethical imperative to allow dual eligibility, especially given the distinct nature of the two processes.

Autonomy and Patient Choice:

A recurring theme throughout the discussion was the importance of preserving patient autonomy. Members emphasized that patients should not be forced to choose between trial participation and waitlisting if they meet the criteria for both. A member added that requiring such a choice could be coercive, particularly when the two options are not equivalent in terms of risk and benefit.

Right to Withdraw and Informed Consent:

A member posed a hypothetical scenario in which a patient enrolled in a xenotransplant trial is suddenly offered a deceased donor organ. She questioned whether the patient could withdraw from the trial at that point and accept the organ. The Vice Chair responded that under research ethics norms, patients have the right to withdraw from a clinical trial at any time, for any reason. The Group 1 Lead reinforced this point by noting that even in standard transplant care, patients often defer offers, further underscoring the importance of patient choice.

Overlap with Other Groups and Future Considerations:

Several participants, noted that some of the issues discussed—such as post-transplant outcomes and reactivation on the waitlist—fall under the purview of Groups 2 and 3. However, they agreed that it was important for Group 1 to acknowledge these intersections and maintain clear boundaries in their analysis.

Equity and Justice:

A member highlighted the need to ensure that patients with living donors are not penalized or deprioritized on the deceased donor waitlist. She stressed that ethical principles such as fairness and respect for patient choice must remain central to the committee's recommendations.

Conclusion of Discussion:

The discussion concluded with a consensus that dual eligibility is ethically permissible under current conditions, provided that eligibility criteria remain distinct and that patient autonomy is respected. The committee agreed that future developments—such as xenotransplantation becoming standard care—may necessitate a reevaluation of these positions.

Upcoming Meeting(s)

- June 26, 2025

Attendance

- **Committee Members**
 - Andy Flescher
 - Sanjay Kulkarni
 - Sheila Bullock
 - Joel Wu
 - Gloria Chen
 - Lois Shepard
 - Laura Jokimaki
 - Felicia Wells-Williams
 - Lisa Paolillo
 - Megan Urbanski
 - Jennifer Dillon
 - Fisayo Adebisi
 - Sena Wilson Sheehan
 - Matthew Wilkinson
- **HRSA Representatives**
 - None
- **SRTR Staff**
 - Bryn Thompson
- **UNOS Staff**
 - Cole Fox
 - Emily Ward
 - Ross Walton
 - Lindsay Larkin