OPTN Ethics Committee
Meeting Summary
August 21st, 2025
Teleconference

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

Introduction

The Ethics Committee ("Committee") met via teleconference on 8/21/2025 to discuss the following agenda items:

1. Welcome and Announcements
2. Group 3 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

No decisions made.

Regional meetings and the public comment period were scheduled from August 27 to October 1. Committee members were encouraged to attend and bring back feedback. The Ethics Committee will provide a comment on the multi-organ transplant proposal, though it will not be presented to the Committee.

Members were reminded where on the Organ Procurement and Transplantation Network (OPTN) website to review Health Resources and Services Administration (HRSA)directives and associated documents.

Updates were shared on the Allocating Organs Out of Sequence (AOOS) workgroup, with a member noting that the kickoff meeting was introductory and no subgroup assignments had been made yet. A new Living Donor Committee-led Workgroup was formed in response to reports of four living donor suicides. Two members volunteered to participate.

Staff also outlined the drafting timeline for the Xenotransplantation white paper being developed. Group leads are to submit drafts by September 8, with full Committee review meetings scheduled for October 1 and October 16. A final vote to send the paper to the Policy Oversight Committee is planned for November 20. Drafts will be compiled and put into a member only Google Drive website, and editing will be done in suggesting mode to streamline collaboration.

Summary of discussion:

None

Next steps:

None.

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

The Committee discussed major questions determined to be addressed for the Xenotransplantation white paper. No decisions made.

Summary of Presentation and Discussion:

The Group 3 presentation and discussion, led by the group lead, explored how prior receipt of a xenotransplant should affect eligibility for a subsequent deceased donor allograft. The group structured their analysis around three scenarios, each representing a different stage in the evolution of xenotransplantation.

Scenario 1: Xenograft as Standard of Care

In this hypothetical future, xenografts are considered equivalent to deceased donor allografts. The group argued that prior receipt of a xenograft should not affect eligibility for future listing. Xenograft recipients would be treated like any other transplant recipient, with access to standard rescue pathways in case of graft failure. This scenario assumes that xenografts provide meaningful benefit and that their outcomes rival those of traditional allografts. The group emphasized the importance of patient autonomy and transparency, especially if organ-specific committees (e.g., lung or heart) determine that xenografts preclude future transplants.

Scenario 2: Xenograft as Clinical Trial for Ineligible Patients

This scenario was based on real cases, such as the first xenograft heart transplant recipient who was ineligible for the traditional waitlist. The group viewed xenografts in this context as bridge therapies. If the xenograft fails, the patient should not be eligible for urgent relisting, as they were never eligible for a deceased donor transplant to begin with. The group stressed the need for informed consent, ensuring patients understand that participation in a clinical trial does not guarantee future access to traditional transplants. They also cautioned against creating undue inducement by implying that trial participation could lead to priority.

Scenario 3: Xenograft Chosen Over Waitlist

In this scenario, patients eligible for the waitlist opt for a xenograft instead. The group supported eligibility for relisting if the xenograft fails, especially if it had provided meaningful benefit. They also supported urgent relisting in cases of acute failure (e.g., primary non-function or thrombosis), distinguishing this scenario from the previous one. The ethical complexity arose when considering patients with functioning xenografts who wished to return to the waitlist. While medically they might not qualify (e.g., Glomerular filtration rate (GFR) greater than 20), the group emphasized that ethically, patients should retain the right to withdraw from the trial and seek standard care.

The second major topic addressed whether xenograft recipients should receive special consideration—priority points—for subsequent deceased donor allografts.

The group unanimously agreed that recipients whose only option was a clinical trial should not receive priority points. These individuals were not eligible for traditional transplants prior to the xenograft, and thus should not gain priority post-failure. The xenograft itself was considered a benefit, and offering additional priority could create undue inducement for trial participation

For patients who were eligible for the waitlist and chose a xenograft instead, the group was more open to granting priority points. They drew parallels to living donors, who receive priority for future

transplants due to their contribution to the transplant community. Xenograft recipients, by opting for experimental treatment, may similarly reduce demand on the donor pool. However, the group acknowledged the risk of undue inducement and debated whether this contribution was equivalent to that of living donors

As a compromise, the group proposed allowing xenograft recipients to remain inactive on the waitlist for a set period (e.g., 3–12 months) to assess graft efficacy. This approach would prevent disadvantage without offering undue benefit. It also aligned with ethical principles by preserving patient autonomy and avoiding coercion. The group noted that this proposal diverged from Group 2's stance, which suggested removing patients from the waitlist entirely after receiving a xenograft.

The discussion highlighted key ethical principles: obligatory beneficence, respect for persons, utility, fairness, and therapeutic misconception. Participants emphasized the need to ensure trial participants were not worse off and to avoid creating incentives that could inhibit decision-making.

Next steps:

Each of the three group leads to submit drafts of their respective white paper sections to staff by September 8th.

Upcoming Meeting(s)

- October 1, 2025, teleconference

Attendance

- **Committee Members**
  - Sena Wilson-Sheehan
  - Laura Jokimaki
  - Gloria Chen
  - Laura Madigan-McCown
  - Lisa Paolillo
  - Joel Wu
  - Shelia Bullock
  - Sanjay Kulkarni
  - Felicia Wells-Williams
  - Grace Lee-Riddle
  - Jennifer Dillon
  - Fisayo Adebiyi
- **HRSA Representatives**
  - None
- **SRTR Staff**
  - None
- **UNOS Staff**
  - Emily Ward
  - Lindsay Larkin
  - Joel Newman
  - Tory Boffo