OPTN Ethics Committee
Meeting Summary
March 20th, 2025
WebEx Meeting

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

Introduction

The Ethics Committee ("Committee") met via WebEx teleconference on 3/20/2025 to discuss the following agenda items:

1. Welcome and Announcements
2. Project Planning: Xenotransplantation White Paper
3. April Meeting Preview

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

1. Welcome and Announcements

- The will formerly in person Ethics Meeting in Detroit is converted to a virtual meeting on April 2, 2025.
- Please add to the Xenotransplantation project literature review.
- Request for a replacement Kidney Expedited Workgroup Ethics representative
- Please respond to the OPTN Board email to notify the contractor to extend Committee membership by one year. This applies to all committee members. If a member is not extending, please notify Committee leadership.

2. Project Planning: Xenotransplantation White Paper

Summary of Discussion

The meeting began with an introduction on the topic of ethical analysis for xenotransplantation. The discussion aimed to compare xenotransplantation to other technologies like biomedically engineered organs and non-human holographs. The focus was on understanding the unique risks and benefits associated with xenotransplantation.

One member emphasized the importance of allowing clinical trial participants to remain on the waiting list, arguing that their participation is primarily for the benefit of future medical advancements rather than personal gain. This principle, they suggested, should apply to all comparable technologies, not just xenotransplantation.

Another member raised questions about the ethical implications of xenotransplantation coming from another species. They suggested that the unique hazards or harms associated with xenotransplantation might warrant special consideration.

A different member highlighted the potential for disease transmission from animals to humans in xenotransplantation. They pointed out that our understanding of animal-to-human disease transmission is less comprehensive than human-to-human transmission, which could pose additional risks.

Another member questioned whether the risks of xenotransplantation outweigh the benefits compared to human organs. The discussion then compared xenotransplantation to other substitute technologies, emphasizing the need to consider these factors in the ethical analysis.

One member emphasized the need to consider equity and access to xenotransplantation if it becomes successful. They raised concerns about the potential high costs and limited access to xenotransplantation. Additionally, they discussed the impact of xenotransplantation on living and deceased organ donation, suggesting that successful xenotransplantation might reduce the drive for traditional donations.

Another member discussed the importance of reimagining patient selection and risk stratification for allocation in light of xenotransplantation. They emphasized the need to consider how this new technology could shift the availability of scarce resources.

A different member expressed concerns about how xenotransplantation might affect a patient's ability to be listed and the scrutiny they might face. They highlighted the potential impact on waitlist mortality metrics and the need for clear guidelines.

The Committee debated whether participation in a clinical trial impacts eligibility and timing for waitlisting. One member raised a distinction between eligibility to participate in the trial and the impact on eligibility for waitlisting. It was suggested to consult an expert for further clarification on this issue.

Another member pointed out that current eligibility criteria for xenotransplantation trials require patients to not be candidates for human allographs. They suggested that as xenotransplantation evolves, its impact on listing might change, potentially allowing simultaneous listing for both xenotransplantation and human allographs.

A different member proposed framing the question around participation in a clinical trial rather than eligibility, as criteria can vary across different trials and locations.

The committee will divide into three groups to address major questions related to xenotransplantation. Each group would lead an Ethics committee meeting and prepare an overview for consideration.

Staff explained the use of a shared drive for collaboration and editing. It was recommended to keep the current meeting time for independent group meetings, suggesting the first meeting could be on April second.

Next Steps

Staff will send links to the literature review and requests members also complete the group survey by Monday, March 24th.

3. April Meeting Preview

Summary of Discussion

The next meeting will be virtual with a 30-minute break. Dr. Jeffrey Stern and Dr. Peter Reese are invited to present on topics related to xenotransplantation. The committee plans to have breakout group discussions to structure their work and organize their subcommittees.

Dr. Jeffrey Stern, a transplant surgeon at NYU, is expected to provide practical insights into xenotransplantation. Dr. Peter Reese, a former chair of the Ethics committee, will discuss theoretical and ethical considerations.

The committee will have time for breakout group discussions to structure their work and organize their subcommittees

Upcoming Meeting(s):

- April 2nd, 2025

Attendance

- **Committee Members**
  - Andy Flescher
  - Sheila Bullock
  - Joel Wu
  - Grace Lee-Riddle
  - Gloria Chen
  - Lois Shepard
  - Laura Jokimaki
  - Felicia Wells-Williams
  - Lisa Paolillo
  - Megan Urbanski
  - Jennifer Dillon
  - Laura Madigan-McCowan
  - Sena Wilson-Sheehan
  - Fisayo Oluwafisayo
- **HRSA Representatives**
  - None
- **SRTR Staff**
  - Bryn Thompson
- **UNOS Staff**
  - Cole Fox
  - Emily Ward
  - Kristina Hogan