

**OPTN Ethics Committee
Meeting Summary
January 16th, 2025
WebEx Meeting**

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

Introduction

The Ethics Committee (“Committee”) met via WebEx teleconference on 1/16/2025 to discuss the following agenda items:

1. Welcome and Announcements
2. Update on AOOS White Paper
3. Project Planning: Ethical Analysis of Possible Impacts of Xenotransplantation on Human Allograft Organ Allocation

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

1. Welcome and Announcements

- There will be an in person Ethics Meeting in Detroit on April 2, 2025.

2. Update on AOOS White Paper

The Chair discussed the postponement of the Ethics committee's paper on Allocating Organs Out of Sequence. The Chair emphasized how the Committee and staff communicated with HRSA frequently during project development. Ethics committee papers guide policy, but do not create it. HRSA referenced a pending critical comment for the reason the paper can not go out for Public Comment. Leadership was able to attend the Policy Oversight Committee (POC) yesterday to advocate that the paper does go out for Public Comment, anyway. A sentiment vote, result not known, was taken at the POC meeting in order to share it with the upcoming Executive Committee meeting. Ethics leadership will also attend the Executive Committee meeting this afternoon to advocate that the paper still go out for Public Comment next week. HRSA comments included that the paper should be postponed but could move forward after the critical comment is resolved. Leadership requests a meeting with HRSA to get more clarification on what postponement means in detail.

The HRSA representative commented that there have been changes in leadership within the (HRSA) division and agency, which may be contributing to the direction to hold the paper from Public Comment. The representative understands this is a postponement, with no intent to prevent this paper from being posted for Public Comment. The Committee has communicated frequently along the way.

The Ethics Committee wants to meet with HRSA leadership to discuss concerns and emphasize the importance of their work. The Chair emphasized the dedicated work of the Committee. It is important that the Committee’s work continue and create papers that bring light to issues before they arise. The paper is not prescriptive.

Summary of Discussion

A Committee member asked about the critical comment. The Chair feels the critical comment has nothing to do with the Committee. The Committee was not asked to respond to it. A link describing the comment letter was provided in the meeting chat function. If community members send letters of concern, HRSA can deem this a “critical comment.” This critical comment includes multiple concerns and HRSA has determined it is relevant to this paper.

A Committee member asked if the content in the comment clashed with the AOOS paper. HRSA did not provide comments about this, specifically. The expeditious taskforce is referenced in the critical comment and the Chair emphasized this is not the work of the Ethics Committee.

Another committee member emphasized that the paper is descriptive and confusion about the problem with the contents of the paper.

Staff commented that HRSA mentioned there could be legal implications. A Committee member commented that the white paper could be opening legal risk.

A Committee member is frustrated with the timing of this pause since members directed so much time, effort, and travel into the creation of the white paper.

Criticisms about the paper from POC reviewers included feedback on not engaging patients in the project process, and lack of data. The Committee noted in the paper that data limitations do exist.

Next Steps

HRSA directed the paper to be held from Public Comment. The Executive Committee will meet this afternoon to discuss the matter. The Committee will receive an update when there is one available. Regional meeting preparation sessions are still scheduled for Committee members.

The Committee will hear the Multi Organ request for feedback proposal and will create a formal comment in February at the full committee meeting.

3. Project Planning: Ethical Analysis of Possible Impacts of Xenotransplantation on Human Allograft Organ Allocation

The Xenotransplantation (Xeno) project is already approved. A memo about this project was shared with HRSA and the response was supportive of the project. The paper will focus on how xeno will interface with the human allograft allocation system and also evaluate ethical issues related to appropriate access for candidates and recipients. The project is expected to go to Public Comment in January 2026.

The approved project scope was reviewed. It will not include changes to policy or data, questions about privacy rights, animal rights, or human subject ethics questions.

The main four questions developed for the project form were also reviewed:

1. How does eligibility to participate in a xenotransplant clinical trial impact the eligibility for and timing of a patient's initial waitlisting for a deceased donor allograft?
2. How, if at all, should receiving a xenotransplant in a clinical trial impact a patient's continuing active status on the allograft waiting list?
3. How should prior receipt of a xenotransplant affect eligibility to be listed for a subsequent deceased donor allograft? (the question of compensating for harms and accounting for benefits)
4. Should former clinical trial participants with a failed xenograft receive special consideration for subsequent receipt of a deceased donor allograft? (the question of priority points)

Three groups will be formed to address the questions. Questions 3 and 4 will be included in one group. Speakers for meetings are being arranged.

Next steps:

Staff will send a link to the Committee to add publications to a shared Literature Review Document. Please send any additional speaker ideas.

Upcoming Meeting(s)

- February 20th, 2025

Attendance

- **Committee Members**
 - Andy Flescher
 - Sanjay Kulkarni
 - Sheila Bullock
 - Julie Spear
 - Gloria Chen
 - Sena Wilson-Shaheen
 - Lois Shepard
 - Laura Jokimaki
 - Jennifer Dillon
 - Fisayo Adebisi
 - Felicia Wells-Williams
- **HRSA Representatives**
 - Jim Bowman
- **SRTR Staff**
 - Bryn Thompson
- **UNOS Staff**
 - Cole Fox
 - Emily Ward
 - Kristina Hogan
 - Laura Schmitt
 - Rebecca Murdock