

**OPTN Ethics Committee  
Meeting Summary  
February 20th, 2025  
WebEx Meeting**

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

## **Introduction**

The Ethics Committee (“Committee”) met via WebEx teleconference on 2/20/2025 to discuss the following agenda items:

1. Welcome and Announcements
2. Q and A: Rich Formica, OPTN President
3. Public Comment Presentation: Establish Comprehensive Multi-Organ Allocation Policy

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.
- There is a new Committee Members, Grace Lee-Riddle, representing Region 2.
- All regional meetings are virtual. Please check the OPTN website provided for meeting dates and agendas.
- Please add to the Xenotransplantation project literature review.
- Two Xenotransplantation speakers are scheduled: Peter Reese (March) and Jeffrey Stern (April).

### **2. Q and A: Rich Formica, OPTN President**

There are many changes from different directions, due to the new administration, but this should not continue. The OPTN President decided to hold all regional meetings virtually to be consistent. News about any change to the in person Committee meeting will be known by the end of February. The Allocation Out of Sequence White Paper (AAOS, which was finished but did not go out for Public Comment) is excellent and there is hope the public will see it soon. Concurrent with the paper, a critical comment was sent to the Secretary of Health and Human Services (HHS). HHS asked the Board what will be done, and the expeditious task force work was paused and the Board provided a response to HHS. The release of the AOOS paper was paused, while the Committee awaits a response to see if they would like to make any changes to the paper based on the response. There is no response yet. The Executive Committee identified this as a problem in July of 2023, and demonstrates that the OPTN has been actively been working on trying to solve a problem. There is an Executive Committee meeting Tuesday and Rich will recommend this go out for public comment soon. It is unclear how this could violate the final rule.

### Summary of Discussion

A member asked about HRSA staffing changes that may impact the community. The Director of Transplantation was impacted by Department of Government Efficiency (DOGE) and some other key staffers were affected. It is a hope that they will be reinstated. It is concerning that HRSA increased staffing recently to manage the complexity of the system.

There is a drop in morale among the Ethics Committee, and this is across all Committees. It is hopeful work and operations will return to normal soon.

A Board member led a group to quantify in dollars the amount of time the volunteers put into the OPTN. The financial equivalent of the volunteer hours is almost as much as the entire OPTN contract dollar amount.

The AOOS paper will be considered again next week by the Executive Committee. The Board President believes that HRSA is not trying to prevent this from eventually going out for public comment. Will putting this paper out for public comment hurt its chances of Board approval? It is too far in advance and hard to prognosticate at this point in time.

Are you anticipating media coverage for AOOS? It is likely someone wants to write something about this.

### Next Steps

The Committee hopes to hear an update about the status of the paper next week.

### **3. Public Comment Presentation: Establish Comprehensive Multi-Organ Allocation Policy**

The Multi-Organ Transplantation (MOT) Committee Vice Chair presented an overview of the request for feedback to establish comprehensive multi-organ allocation policy. The presentation and full proposal can be found on the OPTN public comment website: <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/establish-comprehensive-multi-organ-allocation-policy/>

### Summary of Discussion

A member asked what is better about the new way versus the old way of allocation. The goal is to have consistency among high stakes/high risk sick patients. Organ procurement organizations are put in the middle of clinicians who want organs for their patients.

What about multi-visceral candidates? They will not lose the opportunity to get a transplant due to multi organ allocation, correct? Correct and multivisceral representatives served on the committee and vetted this. The Committee is still finalizing all of the scenarios, but it should not change the way multivisceral candidates are allocated organs.

There were strong feelings by MOT members about highly sensitized candidates and should be handled by exceptions to get access to organs. Can kidneys pull other organs, for example? No plan for this.

If one of the organs gets declined, how are organs reallocated? It would be an expedited allocation scheme.

### Next Steps

The Ethics Committee will create a public comment to post on the website.

### **Upcoming Meeting(s)**

- March 20<sup>th</sup>, 2025

## Attendance

- **Committee Members**
  - Andy Flescher
  - Sanjay Kulkarni
  - Sheila Bullock
  - Joel Wu
  - Grace Lee-Riddle
  - Julie Spear
  - Gloria Chen
  - Lois Shepard
  - Laura Jokimaki
  - Felicia Wells-Williams
  - Bob Truog
  - Lisa Paolillo
  - Megan Urbanski
  - Jennifer Dillon
  - Laura Madigan-McCowan
- **HRSA Representatives**
  - None
- **SRTR Staff**
  - Bryn Thompson
  - Maryam Valapour
- **UNOS Staff**
  - Cole Fox
  - Emily Ward
  - Kristina Hogan
  - Sarah Roache
  - Joel Newman
  - Kaitlin Swanner
- **Other Attendees**
  - Rich Formica, OPTN President
  - Zoe Stewart-Lewis, Multi Organ presenter