

## **OPTN Ethics Committee**

### **Meeting Summary**

**February 1, 2024**

**Conference Call**

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

### **Introduction**

The Ethics Committee (“Committee”) met via WebEx teleconference on 2/1/2024 to discuss the following agenda items:

1. Welcome and Announcements
2. Living Donor Access White Paper: Updates and Discussion

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

#### **1. Welcome and Announcements**

OPTN contractor staff issued a reminder regarding the in-person meeting that is set for Thursday, March 14, 2024, in Houston, TX. Additionally, attention is drawn to a special public comment period concerning an Expedited Placement Variance proposal from the Executive Committee. OPTN contractor staff highlighted that this comment period is open until February 4, 2024, encouraging individuals to submit their feedback on the proposal via the OPTN website.

OPTN contractor staff also reminded the Committee that it was time to register for their regional meeting. Members were directed to visit the OPTN website to register for their regional meeting.

#### Summary of discussion:

A Committee member shared her insights from a recent meeting. She highlighted that the variance mentioned in the proposal only permits running PDSA cycles until July 2025. She clarified for the group that any measures considered for permanent adoption would still need to undergo the standard approval process by other OPTN committees.

#### **2. Living Donor Access White Paper: Updates and Discussion**

The Chair updated the group on their living donor project. In addition, he proposed three new project ideas from which the Committee could choose to pursue.

#### Presentation Summary:

The Chair provided an overview of the living donor project that was initially endorsed by the Policy Oversight Committee (POC), which was subsequently halted by the Executive Committee. Despite the pause, the Chair noted that there remains potential for the Ethics Committee to pursue a narrower iteration of the project. This new iteration of the project proposal focused on whether it is ethical for the OPTN to actively promote living donation more broadly. Principles such as utility, equity, and autonomy would guide the analysis, with a narrower scope on exploring barriers to living donation. Alternative projects suggested by the Chair included xenotransplantation, contingent upon justifying its relevance to HRSA, and examining issues of equity within the context of the OPTN Waiting List. Furthermore, the Vice Chair proposed a third project examining the ethical implications of increased

open organ offers and instances of out of sequence allocation by Organ Procurement Organizations (OPOs). This project would assess factors such as utility, non-use, and equity concerns arising from candidates being bypassed in the allocation process.

Summary of discussion:

The Vice Chair elaborated on feedback received from the POC regarding the initial living donor proposal, expressing difficulty in deriving cohesive conclusions from it. He highlighted the significance of narrowing the project scope to address prevalent questions within the community more effectively. Emphasizing the importance of articulating the ethical considerations surrounding the expansion of living donation, the Vice Chair endorsed the refined project, believing its focused nature would yield more valuable insights. He expressed support for the new project, envisioning it as a steppingstone towards deeper engagement with living donation in the future.

The Chair expressed a preference for spearheading the narrower and expedited living donor project initially. He clarified that while a new write-up would be required, it wouldn't necessitate re-approval from the POC since the original project had received approval. However, it would need approval from the Executive Committee, given its initial rejection. Following the completion of the living donor project, the Committee could draft a memo to support the argument to HRSA regarding xenotransplantation being in the purview of NOTA. Subsequently, once the argument is submitted to HRSA, the Committee would proceed and pursue the third project concerning the ethical implications of open offers and out of sequence allocation.

A member proposed prioritizing the xenotransplantation topic due to its anticipated greater support compared to the previously rejected living donor proposal. They suggested collaboration with the Living Donor Committee to explore potential directions, expressing concern that pursuing the living donor proposal might lead to project rejection or overlap with the Living Donor Committee's focus. The Chair responded, highlighting the current obstacle of lacking HRSA approval for xenotransplantation, necessitating the drafting of a memo.

Another member clarified that a xenotransplantation project wouldn't broadly cover the topic itself but would specifically delve into how xenotransplantation interacts with allocation and the OPTN Waiting List. They provided an example scenario where a patient undergoing xenotransplantation experiences organ failure, prompting questions about their status on the OPTN Waiting List and the ethical considerations involved. Additionally, the OPTN contractor staff clarified that the Living Donor Committee would not have its own project focusing on living donation issues. Instead, they would likely compile a list outlining potential stakeholders, barriers to living donation, and strategies to enhance or expand living donation initiatives.

A member emphasized the importance of carefully framing a paper or project related to xenotransplantation. They noted that the questions regarding xenotransplantation, allocation, and the OPTN Waiting List could also apply to other scenarios such as artificial transplantations, indicating a potentially broader scope than initially considered. The Chair acknowledged the significance of this perspective and highlighted the need to determine whether the project should be framed as xenotransplantation-specific or more broadly applicable.

A participant expressed support for the proposed projects but highlighted the urgency of addressing issues surrounding open organ offers and allocation out of sequence, noting their immediate impact on patients. They suggested prioritizing this project over others, indicating that it should be addressed sooner rather than later. However, the Chair raised concerns about potential delays and loss of momentum if they were to prioritize the allocation out of sequence project before the living donor project. Despite these concerns, he acknowledged the importance of the suggestion.

Several members echoed the sentiment that addressing allocation out of sequence was timely and held more immediate value for the transplant community. They emphasized the need to avoid a reactive approach and address the issue proactively. The Chair sought clarification from the OPTN contractor staff regarding the feasibility of restarting the living donor project after a delay. The staff indicated that while restarting the project had not been difficult in the past, the timing of revival could impact its approval, particularly in light of any upcoming strategic plans.

A Committee member inquired about the possibility of merging the living donor and xenotransplantation topics into a single paper. The Chair responded that due to the distinct nature of these topics, combining them might not be feasible. Additionally, since they lacked approval from HRSA for xenotransplantation, they couldn't pursue it concurrently with the living donor project.

A HRSA representative advised the Committee to consider the potential impact of each project they choose to pursue. For instance, if they prioritize the living donor project first, they should assess how it would promote and encourage living donation. The representative shared the perspective that most people agree that living donation is beneficial and appropriate. Therefore, he urged the Committee to evaluate whether a project aimed at actively promoting or encouraging living donation would significantly impact or make a difference.

The Chair of the Committee encapsulated the collective sentiment, indicating a preference to prioritize the allocation out of sequence project to ensure its timely and relevant resolution. Concurrently, they could plan to draft a memo for a project centered on xenotransplantation, contingent upon receiving approval from HRSA. Once the allocation out of sequence project is concluded, the Committee may assess whether to proceed with the xenotransplantation endeavor if greenlit, or alternatively, revisit the living donor project for further consideration.

#### Next steps:

The Committee will continue to talk about these projects in depth at their in-person meeting on March 14, 2024.

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

- February 15, 2024
- March 7, 2024
- March 14, 2024

## Attendance

- **Committee Members**
  - Andy Flescher
  - Sanjay Kulkarni
  - Sheila Bullock
  - Laura Butler
  - Andrew Courtwright
  - Laura Jokimaki
  - Keren Ladin
  - Lisa Paolillo
  - Ehab Saad
  - Lois Shepherd
  - Erica Stohs
  - Bob Truog
  - Megan Urbanski
  - Felicia Wells-Williams
  - Sena Wilson-Sheehan
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Bryn Thompson
- **UNOS Staff**
  - Kieran McMahon
  - Cole Fox
  - James Alcorn
  - Terry Cullen
  - Joel Newman
- **Other Attendees**
  - Lisa Stocks