

**OPTN Ethics Committee**

**Meeting Summary**

**September 14, 2023**

**Conference Call**

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

## **Introduction**

The Ethics Committee (“Committee”) met via WebEx teleconference on 09/14/2023 to discuss the following agenda items:

1. Update on Liver and Intestine Continuous Distribution (Public Comment Presentation)
2. Efficiency and Utilization in Continuous Distribution Request for Feedback (Public Comment Presentation)
3. Concepts for a Collaborative Approach to Living Donor Data (Public Comment Presentation)

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

### **1. Update on Liver and Intestine Continuous Distribution (Public Comment Presentation)**

The Committee heard a presentation from the OPTN Liver and Intestine Transplantation Committee.

#### Presentation summary:

This request for feedback builds upon the 2022 concept paper for liver and intestine continuous distribution, provides an overview of the project’s development process and progress, and offers next steps for continuous distribution of livers and intestines. The paper also requests community feedback that will assist the Liver and Intestinal Organ Transplantation Committees’ work.

#### Summary of discussion:

A member noted that patients with alcoholic liver disease may have been overlooked, as the MELD score (Model for End-Stage Liver Disease) does not reflect their sickness. They added that they felt the disparity between women and men should be considered when analyzing the muscle mass for MELD.

#### Next steps:

The Committee will provide a summary of the feedback for the Liver and Intestines Committee.

### **2. Efficiency and Utilization in Continuous Distribution Request for Feedback (Public Comment Presentation)**

The Committee heard a presentation from the OPTN Kidney Transplantation Committee.

#### Presentation summary:

This request for feedback builds upon the previous Kidney Transplantation and Pancreas Transplantation Committees’ papers on their continuous distribution projects. This paper requests community feedback on specific operational topics that will assist the Kidney and Pancreas Committee’s work.

#### Summary of discussion:

A member noted that there were slight differences in the transplant rates by race. While they agreed they were not substantial, they encouraged the Kidney Committee to be mindful of them. They added that it would be beneficial for interpretations to be provided for each of the figures from the concept paper.

The Chair suggested that there should be careful distinction between point incentivization for prior living donors and protecting living donors. In addition, the barriers to living donation should continue to be examined, especially when examining the equity of available living donors.

#### Next steps:

The Committee will provide a summary of the feedback for the Kidney and Pancreas Committee.

### **3. Concepts for a Collaborative Approach to Living Donor Data (Public Comment Presentation)**

The Committee heard a presentation from the OPTN Living Donor Committee.

#### Presentation summary:

The OPTN Living Donor Committee has been discussing opportunities to collect data to analyze long-term outcomes of living donation and barriers to living donation. Due to the barriers associated with collecting extended living donor follow-up data from transplant programs and the consensus that longer-term data are needed, the Committee determined that some other entity, such as a registry, is better situated to connect directly with living donors. As such, the Committee has been collaborating with the Scientific Registry of Transplant Recipients (SRTR) to develop a potential future state of living donor data collection. The concept paper explores and discusses the possibilities of this future state and seeks community feedback.

#### Summary of discussion:

A member supported the intent of the project, especially surrounding the gathering of data required for policy development that is not currently gathered. Furthermore, they supported this specific approach to increasing living donation. They requested further clarification on the definition of a “living donor candidate”, as different programs may interpret this differently. In addition, they noted that two years is a long period of time to track a healthy living donor. The Committee recommends examining technological opportunities for tracking these donors to increase participation. Finally, they recommended that a comprehensive ethics review of consent, disclosure, and privacy protections is performed.

A second member agreed it was difficult to continue tracking living donors for two years, noting that response rates for six months and one year were much higher than the two-year follow-up. These donors, they stated, were individuals who were very invested in the process, as they continued through till donation; given that individuals who did not donate are likely less invested, it cannot be expected that follow-up will be more feasible, especially through conventional routes. Concluding, they concurred that a standardized definition for “living donor candidate” would need to be identified given the different screening methods used by programs to evaluate potential living donors.

Another member added that an ethics review should inform these potential donors not just of consent, disclosure, and privacy protections, but also where their data may be used. They also suggested that the Living Donor Committee consider using a unique ID number that is generated rather than the living donor candidate’s social security number.

Next steps:

The Committee will provide a summary of the feedback for the Living Donor Committee.

**Upcoming Meeting**

- October 5, 2023

## Attendance

- **Committee Members**
  - Andrew Flescher
  - Sanjay Kulkarni
  - Melissa Anderson
  - Bob Truog
  - Lois Shepherd
  - Megan Urbanski
  - Jen Dillon
  - Keren Ladin
  - Laura Jokimaki
  - Erica Stohs
  - Lisa Paolillo
- **HRSA Representatives**
  - Marilyn Levi
  - Jim Bowman
- **SRTR Staff**
- **UNOS Staff**
  - Kieran McMahon
  - Kayla Balfour
  - Kayla Temple
  - Cole Fox
  - Joel Newman
  - Matt Cafarella
  - Kristina Hogan
  - Lindsay Larkin
- **Other Attendees**
  - Jim Kim