

**OPTN Living Donor Committee  
Meeting Summary  
November 13, 2024  
Conference Call**

**Steve Gonzalez, MD, Chair  
Aneesha Shetty, MD, Vice Chair  
Introduction**

The OPTN Living Donor Committee (“Committee”) met via Cisco WebEx teleconference on 11/13/2024 to discuss the following agenda items:

1. Project Check-In: Timeline and Getting to Proposal
2. Alignment on Project Approach

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

**1. Project Check-In: Timeline and Getting to Proposal**

The Committee was provided an update on project readiness and timeline.

Summary of Presentation:

The Chair recapped project aim: collect data to understand long-term outcomes of living donation to aid in the Living Donor Committee's goal of improving the informed choice of prospective living donors, and the safety, protection, and follow-up of all living donors.

There are two components of the project:

- Collecting data on all individuals that are evaluated for living donation at transplant programs will provide an appropriate comparator group to analyze the risks and benefits attributable to live organ donation. Data needed: clinical baseline, demographic
- Collecting an individual's living donation decision will allow for analysis regarding equitable access to living donation and reasons for not donating. Data needed: reasons for not proceeding with donation, demographic

The Chair explained the project scope that the Committee has landed on, overall project progress since initial project approval, and the decision to proceed with a phased approach. In prior meetings, the Committee discussed project readiness and timeline. The Chair explained that there has been some feedback from the Workgroup and the OPTN Data Advisory Committee (DAC) that prompted additional discussion about how best to achieve quality data collection in the time remaining. DAC is an operating Committee of the OPTN charged with overseeing all OPTN data collection, and are engaged in collaboration with the Committee to ensure a successful product.

Feedback indicated that some areas of project would benefit from additional time to resolve:

- Qualitative vs quantitative data collection
- Opportunities to further align with current program practice
- Concern for volume of data collection

- Operational questions about putting data collection into practice at programs

DAC leadership indicated that DAC would support taking additional time to think through these aspects further before a proposal is ready. The project has continued support from DAC, the OPTN Policy Oversight Committee (POC), and the community, and there is support for taking the time needed to ensure success. Based on this feedback, LDC leadership agreed that the best course of action is to continue progress on the project, but aim for an extended timeline of public comment period in July 2025. OPTN Board leadership was provided with this update and there was support for moving forward with the adjusted timeline.

## 2. Alignment on Project Approach

No decisions were made.

### Summary of Presentation:

The Chair discussed that it is important to make sure that all Committee members are aligned on approach as the project continues. Goal of discussion: agree on big picture to help the Workgroup build data collection for the project.

Project will find the appropriate balance for data collection to gather

- Baseline clinical and demographic information – this will be required when comparing long-term outcomes with living donors
- Donation decision – the reasons why candidates do not proceed with donation

The Workgroup will help Committee think through the specifics of how to strike this balance using data in an OPTN context, using the Scientific Registry for Transplant Recipients' (SRTR) Living Donor Collective pilot program as a scaffold.

**Risks and benefits to donation:** Data collection will benefit prospective living donors in their ability to make educated decisions regarding the donation process, as well as living donor care teams to provide more evidence-based care and improve consistency in processes. **What types of actions would the Committee like to take following data analysis results?**

**Barriers to donation:** Understanding barriers in access will also help inform and address known inequities in living donation. **What types of actions would the Committee like to take following data analysis results?**

Data collection conversations can be tricky- ideally, the OPTN would have all data.

With the big picture in mind, the WG can answer specific questions to make sure that the Committee is going to get data that achieves the overall project intent.

Workgroup and staff will focus on:

- Data collection across forms
- Ability to collect from an IT perspective
- How each data element should be worded
- How the forms should be laid out

### Summary of discussion:

The Chair discussed that the Committee needs to align on the purpose of collecting data on living donor candidates as a comparator group for long-term outcomes. The Chair noted that is not feasible to

understand every detail for comparisons, however, that the Committee should be able to achieve a generalized sense of increased risk or safety for donation long-term with respect to a few baseline characteristics. The Vice Chair agreed, stating that the Committee can use the generalized information to propose a deeper, more granular project to address any findings in the future. The Chair noted that the Committee would ideally use the information about what risks are associated with the living donation of a specific organ to:

- Improve informed consent processes
- Further refine the organ-specific exclusion criteria
- Develop policies that would further protect groups of people that may be at a higher risk from donation long-term
- Reduce variation in program-specific acceptance criteria by providing additional evidence regarding risk

The Vice Chair stated that with regards to barriers, having a general idea of why people did not proceed to donation will allow for understanding the major categories of barriers, and then the Committee can use that information to focus in on addressing them in the future. Regarding barriers, the Chair explained that the Committee would use the information about why people are not proceeding with donation to:

- Improve transparency regarding program-specific acceptance criteria
- Create policies/initiatives that provide specialized support to people experiencing a particular type of barrier

A member explained that the cohort will not be able to fully answer the questions the Committee is looking to understand because of the challenges with using the comparator group as well as not being able to understand how many people never started an evaluation due to a barrier. The Vice Chair agreed, noting that this project will not be making a true “control group.” A member explained that the SRTR’s portion of the project to collect long-term health outcomes on living donors is the most important part of the project, in their mind. A living donor on the Committee expressed some concern about the SRTR’s living donor follow-up and wanted to ensure that the SRTR is fully established with their follow-up before implementing the project, which would remove the OPTN’s 2-year follow-up of living donors and allow the SRTR to perform annual follow-up for the lifetime of the donor. A representative from SRTR explained that the long-term follow-up of donors is a very exciting portion of the project, but cautioned that without at least some information about living donor candidates to compare that information to, the Committee will not be able to answer the questions about risks/benefits to donation. This representative gave an example, explaining that if the Committee is interested in knowing “what is your risk of chronic abdominal pain if you donate a kidney versus if you do not donate,” that question cannot be answered without the information from the comparator group of those who did not go on to donate. A member noted that it will be important to distinguish between center-driven decline reasons versus living donor candidate-driven decline reasons.

The SRTR representative affirmed that the SRTR is happy to provide information to the Committee and Workgroup to aid decision-making on which data elements are the most appropriate to achieve the goals of analysis.

#### **Upcoming Meetings:**

- December 11, 2024

## Attendance

- **Committee Members**
  - Aneesha Shetty
  - Alexandra Shingina
  - Annie Doyle
  - Anita Patel
  - Ashtar Chami
  - Danielle Reuss
  - Milton Mitchell
  - Michael Chua
  - Nahel Elias
  - Nate Osbun
  - Steve Gonzalez
  - Tiffany Caza
  - Trysha Galloway
  - Frankie McGinnis
- **SRTR Representatives**
  - Caitlyn Nystedt
  - Allyson Hart
  - Katie Siegert
- **HRSA Representatives**
  - None
- **UNOS Staff**
  - Jamie Panko
  - Kieran McMahon
  - Laura Schmitt
  - Sam Weiss
  - Cole Fox
  - Lauren Mooney
  - Sara Rose Wells