

## **OPTN Living Donor Committee Workgroup**

### **Meeting Summary**

**October 9, 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 10/09/2024 to discuss the following agenda items:

- 1. Project Check-In: Timeline and Getting to Proposal**
- 2. Discussion: Living Donor Candidate Definition Protocolization**

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

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

Committee members reached consensus to try to achieve the proposal by January, and if decisions were not able to be made in time, to push the proposal back for public comment in July 2025.

#### Summary of Presentation:

The Chair recapped what the Donation Decision Workgroup has been up to and noted that there was some disagreement between members on how to approach the data collection. The Chair also overviewed the project timeline, and explained that in order to keep the timeline for going out to public comment in January 2025, substantive material should be completed by the end of October so that policy language and monitoring can be discussed in November, to enable a vote on the final proposal in December. From today’s call, there are 2 more Workgroup calls and 2 more Committee calls in which project decisioning can occur.

Staff explained three options in terms of how to proceed regarding timeline:

1. Provide an update to the community and a request for feedback (RFF) on specific areas in January, and then aim to have the proposal ready for July PC.
2. Continue pushing for January, and if the decisions are not able to be made in time, push the project back to July PC without giving an update to the community in the meantime.
3. Request a special public comment period for the proposal.

#### Summary of discussion:

The Chair discussed that a special public comment period would not be feasible because of the risk of getting less community feedback. The Chair explained that he is hopeful that the Committee will be able to complete decisions in time. A member was in favor of converting to an RFF because of the number of sticking points in the project and the potential ability to collect some discrete data in terms of a survey. A member noted that they were more interested in trying to complete the project in the original timeline of January, explaining that specifics can be worked out later if needed. Staff noted that for the proposal, specifics in terms of completed decisions will need to be included at the time of public

comment. A member expressed concern about holidays interfering with scheduling. A member asked if the Workgroup was confident in the timeline and project readiness, and the Vice Chair added that the Workgroup is providing feedback on multiple aspects and this is an ongoing conversation. The Vice Chair explained that she did not believe the core decisions would change based on public comment feedback, so it would be worthwhile to continue moving forward. The immediate past Chair explained that the direction to achieve this faster came from Board leadership.

Committee members reached consensus to try to achieve the proposal by January, and if decisions were not able to be made in time, to push the proposal back for public comment in July 2025.

Members recommended additional surveys so that some project decisions can be accomplished in a shorter timeframe, such as workflow edge cases.

## **2. Discussion: Living Donor Candidate Definition Protocolization**

The Committee reached consensus to define a living donor candidate as an individual undergoing evaluation for donation.

### Summary of Presentation:

The Committee has identified the need to refine the exact, protocolized definition of a living donor (LD) candidate.

Here is what the Committee previously reached consensus on:

- Population to collect data on: those who have begun a LD evaluation but fell out of the process somewhere
- Should be anchored by OPTN Policy
- Will cover in-person clinic and telehealth appointments
- Will NOT include those screened out using programs' online, user-based screening tools
- Will NOT require programs to complete any testing beyond what they have already completed as a part of working up the donor candidate (if the donor only got to blood typing and then withdrew, imaging not required to be completed)

Committee has indicated that ideally, the definition of living donor candidate:

- Should not add extra requirements to the evaluation process
- Should allow for center variation in how they complete the evaluation process as much as possible
  - Centers aren't uniform in the order in which they perform the evaluation components so it makes it challenging to time box it
  - Centers aren't uniform in the way that they approve and discuss living donor candidates
- Should be clearly understood by programs
- Should capture people who passed "screening" and begun an evaluation, and then "fell out" of the process for any reason
  - Either the LD candidate themselves withdrew OR
  - The center determined that the LD candidate was not suitable for donation

The Committee was presented with three potential options in line with these constraints:

**1. Mirror the language already included in policy regarding Independent Living Donor Advocate (ILDA)**

“A living donor candidate is an individual undergoing evaluation for donation”. How this would work:

- What constitutes an evaluation is already defined by *OPTN Policies 14.1-14.4*. The Committee has not indicated that this project should change what constitutes a living donor evaluation.
- Programs could be monitored on this timeframe/process similar to how it is monitored for ILDA now.

**2. Add an informed consent requirement into policy**

How this would work: Committee could propose specifying that informed consent for the evaluation process is obtained and documented. Then, anyone who has completed this “step” of informed consent could be considered a living donor candidate, and data collection would be required.

- This would be consistent with CMS (which requires informed consent regarding the living donor evaluation process), but would be a *change* to the evaluation requirements within the OPTN
- This may pose scope concerns for this option (it wasn't in the original scope to change the informed consent requirements)

**3. Use multidisciplinary selection Committee as an anchor**

Feedback from the in-person suggested making the definition of a living donor candidate someone who has:

- Completed at least one part of evaluation, as defined by *OPTN Policies 14.1-14.4*
- **AND** has been considered by the multidisciplinary selection committee

The recommendation was that this is after screening, and would be adequately capturing the population the Committee is trying to target. However, there are some challenges with this approach:

- Multidisciplinary selection committee is not a component of OPTN Policy now, so it would need to be added in. It is consistent with CMS, but similar to the last option, would require altering policy to get at this population.
- There is significant center variation on who is considered by the selection committee, and how

Summary of discussion:

The Chair explained that the option to mirror the ILDA language is most consistent with what the Committee is trying to achieve. The Vice Chair agreed, noting that it is not disruptive to centers' current practice. A member noted that this option may not be specific enough and explained that it would be a potential option to consider someone a LD candidate when they are assigned an ILDA. However, the Chair explained that the simpler it can be is best, and the Vice Chair noted that by not attaching the policies to each other, it makes changing them easier and reduces the risk of an unintentional change.

The Committee reached consensus to define a living donor candidate as an individual undergoing evaluation for donation.

**Upcoming Meetings:**

- November 13, 2024

## Attendance

- **Committee Members**
  - Aneesha Shetty
  - Ashtar Chami
  - Danielle Reuss
  - Ginger Ireland-Hoffman
  - Milton Mitchell
  - Laura Butler
  - Michael Chua
  - Nancy Martin
  - Nate Osbun
  - Steve Gonzalez
  - Tiffany Caza
- **SRTR Representatives**
  - Caitlyn Nystedt
  - Katie Siegert
  - Krista Lentine
- **HRSA Representatives**
  - Nawraz Shawir
  - Allison Hutchings
  - Mesmin Germain
- **UNOS Staff**
  - Jamie Panko
  - Kieran McMahon
  - Laura Schmitt
  - Sam Weiss