

## **OPTN Living Donor Committee Decision Data Workgroup**

### **Meeting Summary**

**May 8, 2025**

**Conference Call**

**Aneesha Shetty, MD, Chair**

### **Introduction**

The OPTN Living Donor Committee Decision Data Workgroup ("Workgroup") met via Cisco WebEx teleconference on 5/8/2025 to discuss the following agenda items:

- Continue Review and Discuss Mockups: Form B / Living Donor Non-donation Form and existing forms

The following is a summary of the Subcommittee's discussions:

### **Announcements and Updates**

The proposed name for the new form is the "Living Donor Non-Donation Form," a decision made by the full committee a few weeks ago. Today is the last workgroup meeting before the full committee votes on the project next Wednesday.

The Data Advisory Committee (DAC), decided not to endorse their proposal due to significant changes that would compromise the project's goals, such as removing entire sections of the form and concerns about transferring the two-year follow-up to the SRTR. They suggested keeping the follow-up with the OPTN and starting with a pilot instead of requiring all transplant centers to fill out the forms.

**The Living Donor Committee Chair** emphasized the importance of incorporating feedback from the workgroup and the Data Advisory Committee to optimize the project and policy proposal. He acknowledged the contributions of the workgroup members and highlighted the ongoing efforts to refine the Living Donor Non-Donation Form. Public comment is scheduled to start on August 8, and assuming the proposal goes out for public comment, phase two of the proposal will go the Policy Oversight Committee in August. All members of the workgroup can continue to work on Phase II, if approved.

### **1. Continue Review and Discuss Mockup: Form B**

Staff reviewed various items on the forms, prioritizing those needing group discussion. Changes in existing forms were made to align with the new Living Donor Non-Donation Form.

#### Summary of discussion

**Coronary Artery Disease vs. Heart Disease:** The group debated whether to use "coronary artery disease" or "heart disease" in the forms. It was decided to stick with "coronary artery disease" as it is more straightforward and aligns with policy language. The Committee Chair explained that having a history of coronary artery disease may not necessarily be the reason for not donating, as it could be stable and addressed. The group agreed to keep the field simple with a yes/no option.

**History of Obesity:** The intent was to identify individuals who attempted to lose weight prior to undergoing a living donor evaluation. The group discussed the challenges of capturing this data reliably

and decided to remove the field due to its nebulous nature. A member highlighted the difficulty of extracting this information from EMRs and the potential for inconsistent documentation.

**Anatomic or Vascular Variance:** The group discussed whether to keep a single field for anatomic or vascular concerns or separate them into multiple fields. It was decided to retain a single field for anatomic or vascular concerns, including size/volume, anatomic defects, and vascular anatomy, to simplify the form. The Committee Chair suggested using the terms already in policy to cover all relevant aspects.

**History of Malignancy:** The group debated whether to keep granular subtypes of malignancy. A member expressed concerns about the effort required to obtain detailed information and the potential for unknowns. It was decided to simplify the field to a yes/no question for history of malignancy and move broader categories to the donation decision section. This approach aligns with the current living donor registration form, which already captures detailed subtypes.

**Liver Biopsy and Imaging:** The group discussed the necessity of liver biopsy and imaging for determining steatosis. The Committee Chair explained that the medical evaluation for living liver donors requires determining the presence of steatosis, which can be done through biopsy or imaging. The group decided to add options for liver biopsy and imaging separately to ensure clarity. They also discussed the order of questions and agreed to keep the current structure.

## **2. Alignment of the new Living Donor Non-Donation Form with existing forms**

### Summary of Discussion

The group initially considered aligning the existing forms with the new Living Donor Non-Donation Form. This included reviewing fields related to diabetes, hypertension, and malignancy, which differed slightly between the forms. The existing forms collect more detailed information compared to the new form, such as specific subtypes of malignancy and detailed options for diabetes and hypertension. The new form, while comprehensive, has fewer details but covers the same general areas.

The Committee Chair suggested that it might be best to leave the existing forms as they are for now. He emphasized the importance of consistency in data collection and the potential complications of changing forms mid-project. The group agreed that maintaining consistency was crucial and that any changes should be made thoughtfully and comprehensively.

The possibility of conducting a more granular review of all forms in phase two of the project was discussed. This would allow for a comprehensive evaluation and intentional updates to ensure all forms align and capture the necessary data. The group felt that a detailed review in phase two would be the best approach, allowing for thoughtful and intentional updates without disrupting current data collection processes.

The group also debated whether to add fields for history of gestational diabetes and A1C values to the existing forms. These fields were included in the new form but not in the current forms. The workgroup Chair highlighted the importance of these fields, given the changing criteria for living donation and the prevalence of pre-diabetic conditions among donors. Staff raised a concern about whether the lack of alignment between forms would impact the follow-up data needed for the SRTR. The group acknowledged this comment but decided that a more intentional review in phase two would be the best approach.

Ultimately, the group decided to leave the existing forms unchanged for now. They agreed that a detailed review and potential updates would be better suited for phase two of the project. This approach would ensure that any changes are made thoughtfully and comprehensively, without

disrupting current data collection processes. The group also agreed to add patient ID and middle initial to the existing forms to improve tracking and consistency across all forms.

The decision to leave the existing forms unchanged was made to maintain consistency in data collection and avoid complications. The group recognized the importance of a comprehensive review in phase two to ensure all forms align and capture the necessary data. This approach allows for thoughtful and intentional updates, supporting the project's long-term goals.

#### Summary of Decisions from Meeting

<b>Topic</b>	<b>Decision</b>	<b>Details</b>
<b>Form Name</b>	<b>Living Donor Non-Donation Form</b>	<b>Name decided by the full committee.</b>
<b>Coronary Artery Disease vs. Heart Disease</b>	<b>Use "Coronary Artery Disease"</b>	<b>Aligns with policy language; simple yes/no option.</b>
<b>History of Obesity</b>	<b>Remove field</b>	<b>Difficult to capture reliably; too nebulous.</b>
<b>Anatomic or Vascular Variance</b>	<b>Retain single field for anatomic or vascular concerns</b>	<b>Includes size/volume, anatomic defects, and vascular anatomy.</b>
<b>History of Malignancy</b>	<b>Simplify field to yes/no for clinical section</b>	<b>Move broader categories to donation decision section.</b>
<b>Liver Biopsy and Imaging</b>	<b>Add separate options for liver biopsy and imaging</b>	<b>Ensure clarity; keep current structure.</b>
<b>Middle Initial vs. Middle Name</b>	<b>Use "Middle Initial"</b>	<b>Aligns with system-wide data collection.</b>
<b>Patient ID</b>	<b>Add Patient ID to existing forms</b>	<b>Improve tracking and consistency.</b>

Topic	Decision	Details
Existing Forms	Leave unchanged for now	Conduct detailed review in phase two; add patient ID and middle initial.
Phase Two Review	Conduct granular review of all forms	Ensure comprehensive evaluation and intentional updates.
Diabetes Fields	Consider adding history of gestational diabetes and A1C in phase two	Important for tracking pre-diabetic conditions among donors.
Donor Declined Paired Exchange	Add field for donor declined paired exchange	Important for targeting education regarding paired exchange.

#### Next Steps:

The decisions made today will be considered by the Living Donor Committee on May 14, 2025.

#### **Upcoming Meetings:**

- None scheduled at this time.

## **Attendance**

- **Workgroup Members**
  - Trysha Galloway
  - Reza Saidi
  - Annesha Shetty
  - Jennifer Peattie
  - Kate Dokus
  - Michael Chua
  - Stevan Gonzalez
  - Julie Prigoff
- **SRTR Representatives**
  - Caitlyn Nystedt
  - Katie Siegert
- **HRSA Representatives**
  - None
- **UNOS Staff**
  - Asma Ali
  - Emily Ward
  - Lauren Mooney
  - Laura Schmitt
  - Sara Rose Wells