

**OPTN Living Donor Committee  
VCA Workgroup  
Meeting Summary  
March 11, 2020  
Conference Call**

**Stevan Gonzalez, MD, Chair**

## **Introduction**

The Living Donor Committee VCA Workgroup met via Citrix GoToTraining teleconference on 03/11/2020 to discuss the following agenda items:

1. Welcome and Introductions
2. Summary of History, Problem, and Solution
3. Goals of Workgroup and Scope of Project
4. Overview of Project Plan
5. Overview of Policy 14
6. Next Steps

The following is a summary of the Workgroup's discussions.

### **1. Welcome and Introductions**

The Chair welcomed everyone to the call and then each Workgroup member introduced themselves. The Workgroup is comprised of members of the Living Donor, VCA, and Ethics Committees as well as a living uterine donor.

### **2. Summary of History, Problem, and Solution**

The Chair presented the history of living donor policy and the problem and solution statements for the project to update OPTN Policy 14 to include living VCA donors.

#### Summary of Data:

From September 2017- January 2020 there have been 30 uterine transplants, 18 of which have been from living donors. To date, uterus recipients have given birth to eight children in the U.S. For the past 3 years, over half the candidates added to the OPTN VCA waiting list were uterus candidates. Currently, uterus is the most common VCA Waitlist Registrations.

Living VCA donors are currently not covered by *OPTN Policy 14: Living Donation*. Updating language in Policy 14 would fill this gap and establish safeguards for living VCA donors and recipients as this field continues to evolve. This project is being developed in tandem with the VCA Committee's project to update the Living Donor Registration (LDR) and Living Donor Follow-Up (LDF) forms to include living VCA donors.

The proposed solution is to update OPTN Policy 14 to include all living VCA donors and add uterus specific elements. The Workgroup will look at Policy 14 section by section and consider how each policy would apply to VCA living donors and make recommendations to add or delete language as needed. The Workgroup will also assess what living uterine donation-specific requirements need to be incorporated into relevant sections of Policy 14 (ex. informed consent, psychosocial evaluation, etc.). These

considerations will be informed by but not limited to workgroup member expertise as well as IRB protocols of existing VCA programs.

#### Summary of Discussion:

A Workgroup member asked what protocols VCA programs are using now. The Workgroup was informed current programs are operating under their own IRB protocols. Currently these programs aren't required to submit data to the OPTN as other organ type programs do.

The Living Donor Committee Chair mentioned current OPTN Bylaws do not have specific program requirements for VCA programs. This could possibly be addressed in a future project by the VCA Committee or MPSC.

### **3. Goals of Workgroup and Scope of Project**

The Chair reviewed the goals of the Workgroup and scope of the project to update OPTN Policy 14.

#### Summary of Data:

The goals of the Workgroup and scope of the project are to:

- Amend Living Donor Policy to include Living VCA Donors
- Review Policy 14 section by section to incorporate living VCA donors
- Promote living donor safety by requiring regulation for living VCA donors
- Identify uterine specific criteria to include in Living Donor Policy where appropriate

### **4. Overview of Project Plan**

The Workgroup reviewed the project plan and workgroup meeting schedule. The Workgroup will meet five times and have regular check-ins with the Living Donor Committee.

### **5. Overview of Policy 14**

The Workgroup will review each section of OPTN Policy 14 and evaluate if language needs to be added or removed. The Workgroup will pay special attention to the following policy sections:

- 14.1 Psychosocial Evaluation Requirements for Living Donors
- 14.3 Informed Consent Requirements
- 14.4 Medical Evaluation Requirements for Living Donors
- 14.6 Placement of Living Donor Organs

### **6. Next Steps**

Workgroup members were asked to access the project Sharepoint project site and review literature and IRB protocols saved there. Workgroup members should also read through Policy 14 and identify sections for editing prior to the next call.

#### **Upcoming Meetings**

- March 25 – Teleconference
- April 8 – Teleconference