

**OPTN Vascular Composite Allograft
Meeting Minutes
January 8, 2020
Conference Call**

**Linda Cendales, Chair, MD
Bo Pomahac, Vice Chair, MD**

Introduction

The OPTN Vascular Composite Allograft (the Committee) met by teleconference on January 8, 2020 to discuss the following agenda items:

1. Update on Public Comment documents
2. New Project Review and discuss project “Modify Data Collection on VCA Living Donors”
3. Other Significant Items

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

1. Update on Public Comment documents

UNOS staff described the public comment process. The Committee’s public comment documents will go to the Policy Oversight Committee (POC) for approval on 1/13/20 and to the Executive Committee on 1/16/19. The public comment period begins on 1/22/20 and concluding on 3/24/20. These documents will be presented to the Board of Directors (BOD) for approval in June 2020 on the non- discussion agenda.

Summary of discussion:

A Committee member encouraged the Committee to submit public comments individually and on behalf of their institutions.

Next steps:

Outreach for these public comment documents will be targeted to stakeholders in the community close to VCA transplantation. A National webinar will also be held in early February 2020.

2 New Project Review and discuss project “Modify Data Collection on VCA Living Donors”

The Committee’s new project “Modify Data Collection on VCA Living Donors” plans to run in tandem with a Living Donor Committee (LDC) project, “Modify Policy 14 to include living VCA Donors”. The two committees will collaborate and establish a workgroup for each initiative comprised of VCA, living donor, and ethics committee members. These projects will meet two needs:Summary of discussion:

1. Modify Data Collection on VCA Living Donors: Update the data collected on living donors for VCAs. Currently these forms do not contain data that would apply for living VCA donors. These data collection instruments are designed primarily for living kidney and liver donors. Revised data collection requirements are needed as there have been 22 living donors for uterus to date but no mechanism to track the potential impacts on these type of donors. The VCA committee will lead this project.

2. Modify Policy 14 to include living VCA Donors: Develop guidelines for living VCA donation. The Living Donor Committee will lead this project.

Summary of discussion:

The main discussion during this VCA Committee meeting was centered on if the Committee advised that Policy 14: Living Donation should be modified to include only guidelines for living uterus donation or if the policy should speak to living uterus donation in addition to other types of living VCA donations. Muscular skeletal flaps that can be used for soft tissue coverage are an example of a living VCA donation other than uterine.

A few members believed that Policy 14 should be modified to include living uterus donation in addition to other types living VCA donations. Another member favored modifying Policy 14 for only living uterus donors. He reported that surgeons may not consider flaps to be VCAs and perform the procedure without knowledge of an OPTN policy in place. Another member advised that the Committee would need to do outreach prior to the development of guidelines for other living VCA donation in order to make this more widely known.

A member asked about any consequences for a situation in which a surgeon preforms a transplant of an organ that is defined as a VCA in the covered body parts list and their center does not have a VCA registered program or is unaware that a vascularized flap is considered a VCA. UNOS staff reported that a situation like this would likely be processed through the Membership and Professional Standards Committee (MPSC) along with the Executive Committee. A member mentioned past incident where a surgeon transplanted both a kidney and a portion of a vascularized scalp into/onto a patient. Oftentimes in these situations, centers meet all other criterion other than having a registered VCA program. Outreach was suggested to make the community aware of all types of VCA under the Final Rule.

A member asked to view the list of body parts that are considered VCAs under the purview of the OPTN. UNOS staff displayed this list and explained that these approved body parts have been passed by the BOD, but have not yet implemented. This part of VCA policy will be implemented at the same time as the new membership requirements. UNOS staff reported that the Committee did not need to reach a final decision on which VCAs to include in Policy 14 during this meeting, but that members should continue to think on this concept.

A member suggested a staged approach to modifying Policy 14. First, guidelines pertaining to living uterus donation would be developed, followed by guidelines for other living VCA donation. This member advised beginning with living uterus donation, as prevalence of this procedure has increased at a faster rate than other living VCA donations.

The HRSA representative on the call presented the option of adding "any VCA" to Policy 14 in addition to developing specific requirements for uterine donors. Committee members agreed and reported that this option is being discussed with the LDC. A Committee member cautioned that while general guidelines for living VCAs are important, the Committee would not want to inadvertently give the impression that all VCAs are acceptable for living donation. The Committee was presented with a potential timeline for these two projects.

Next steps:

The Committee will continue to consider this important question as the Modify Policy 14 Workgroup forms. UNOS staff will continue to develop a timeline for these projects to present to the Living Donor and VCA Committees. Other Significant Items

Summaries of any additional discussion items. These are important to document they occurred. Such topics could include committee discussion of a Federal Register notice or acknowledgement that the committee reviewed confidential case reports.

Upcoming Meetings

- Feb 12, 2020 (teleconference)
- March 11, 2020 (teleconference)
- April 3, 2020 (In- Person)