Memorandum

To: Transplant Program Administrators
   Transplant Program Primary Surgeons and Physicians
   OPO Executive Directors
   OPO Medical Directors

From: James B. Alcorn, Esq., Director of Policy

Date: January 13, 2015

Re: Use of VCA Grafts to Reconstruct the Abdominal Wall

On July 3, 2014, the OPTN Final Rule (42 CFR part 121) was amended to add vascularized composite allografts (VCAs) as a covered human organ. Oversight of VCA recovery and transplantation has thus come under the auspices of the OPTN.

The OPTN Final Rule (42 CFR §121.2) outlines the criteria that must be met in order for an anatomical structure to be considered a VCA:

A vascularized composite allograft is defined as any body part that meets ALL nine of the following criteria and is not an otherwise described organ for transplantation (such as a kidney, heart, etc.):

1) that is vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation;
2) containing multiple tissue types;
3) recovered from a human donor as an anatomical/structural unit;
4) transplanted into a human recipient as an anatomical/structural unit;
5) minimally manipulated (i.e., processing that does not alter the original relevant characteristics of the organ relating to the organ’s utility for reconstruction, repair, or replacement);
6) for homologous use (the replacement or supplementation of a recipient’s organ with an organ that performs the same basic function or functions in the recipient as in the donor).
7) not combined with another article such as a device;  
8) susceptible to ischemia and, therefore, only stored temporarily and not  
cryopreserved; and  
9) susceptible to allograft rejection, generally requiring immunosuppression that may  
increase infectious disease risk to the recipient.

In the clinical practice of Plastic and Reconstructive Surgery, vascularized composite  
tissue transfers in a single individual, such as free flap procedures, have been done for  
years and are part of standard practice. When such procedures are done between a donor  
and a recipient, the possibility of allograft rejection and the need for immunosuppressive  
medication results in these procedures being considered VCA transplants. Occasionally,  
such a VCA transplant may be done in conjunction with a traditional solid organ transplant  
as part of abdominal wall reconstruction. The VCA Committee was concerned that  
surgeons performing these types of procedures may be unaware of the regulatory  
changes or unaware that a VCA transplant program approval would be required before  
they perform such procedures going forward.

The Committee collaborated with colleagues at the Division of Transplantation at the  
Health Resources and Services Administration (HRSA) to clarify the use of VCAs from  
organ donors in the surgical repair of the abdominal wall. Any vascularized multiple tissue  
transfer (soft tissues and/or bone) used to reconstruct an abdominal wall should be  
considered a VCA. The most commonly used procedure that fits the VCA definition is an  
anterolateral thigh flap which includes fascia and muscle and requires a vascular  
anastomosis. The use of a posterior rectus sheath flap that consists of fascia only and is  
transplanted along with the liver does not require a separate vascular anastomosis and  
does not meet the VCA definition. Donor fascia, donor de-epithelialized skin, and  
AlloDerm are other materials used to reconstruct the abdominal wall, and not VCAs.

Additionally, any vascularized multiple tissue transfer between a donor and a recipient  
(soft tissues and/or bone) used to repair other structural defects in a recipient or  
transplanted to monitor rejection (e.g. vascularized composite transfer as sentinel  
graft) meets the criteria for a VCA organ. Tissues not requiring a vascular anastomosis  
(e.g., tendon, ligament, muscle, nerve, bone, other) do not meet the criteria for VCA.

Before a surgeon can use a vascularized composite allograft from a donor to reconstruct  
the abdominal wall or another structure, the hospital must have:

1) submitted the required application materials and received approval from the  
OPTN to operate a VCA transplant program  
2) registered the patient in need of such a graft as a VCA transplant candidate  
with the OPTN

Transplant Hospitals
Please share this information with surgical colleagues at your institution. If you have  
questions about the application process for a VCA transplant program, please contact
Jacqueline O'Keefe, UNOS Assistant Director, Member Quality (804-782-4857 or jacqueline.okeefe@unos.org).

Approved VCA transplant programs needing assistance adding a VCA candidate to the waiting list can contact the UNOS Organ Center (800-292-9537 or vca@unos.org).

**OPOs**
OPOs must ensure that VCA grafts are only allocated to candidates on the OPTN VCA Candidate List. If any hospital requests a graft that meets all nine criteria for a VCA for use in other surgical procedures for a patient who is not on the OPTN VCA Candidate List, do not allocate a VCA to that patient.