OPTN

Notice of OPTN Policy and Bylaw Changes

Clarification of Policies and Bylaws Specific to Vascularized Composite Allografts

Sponsoring Committee :	**Vascularized Composite Allograft Transplantation**
Policies and Bylaws Affected:	***Policy 1.2: Definitions***
	Policy 2.2: OPO Responsibilities
	Policy 2.14.E: Deceased Donor Authorization Requirement
	Policy 5.4.B: Order of Allocation
	Policy 5.6.A: Receiving and Reviewing Organ Offers
	Policy 5.6.B: Time Limit for Review and Acceptance of Organ Offers
	Policy 12: Allocation of Vascularized Composite Allografts (VCA)
	Policy 12.1: Waiting Time
	Policy 12.2: VCA Allocation
	Policy 14.5.C: Reporting of Living Donor Blood Type and Subtype
	Policy 15.4.A: Host OPO Requirements for Reporting Post-Procurement Donor Results and Discovery of Potential Disease Transmissions
	Policy 18.1: Data Submission Requirements
	Policy 18.2: Timely Collection of Data
	Policy 18.3: Recording and Reporting the Outcomes of Organ Offers
	Bylaws Appendix J: Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs
	Bylaws Appendix M: Definitions
Public Comment:	**N/A**
Board Approved:	**June 14, 2021**
Effective Date:	**June 14, 2021**

Purpose of Policy and Bylaw Changes

These changes better align OPTN Policies and Bylaws with the Final Rule requirement for the OPTN to "identify all covered body parts in any policies specific to vascularized composite allografts,"[1] and clarify whether certain clinical procedures are considered vascularized composite allograft (VCA) transplants.

[1] 42 CFR §121.4(e)(3).

Proposal History

On June 6, 2016, the OPTN approved a proposal entitled *List Covered Body Parts Pertaining to VCA*. This proposal was developed to meet a requirement in the Final Rule for the OPTN to "identify all covered body parts in any policies specific to vascularized composite allografts."[2] Implementation of this proposal was scheduled for June 2021 in conjunction with implementation of updated VCA transplant program membership requirements.

Following a review for Final Rule compliance in December 2020, the OPTN recognized a need to modify the previously approved, but not yet implemented, list of covered body parts. In addition, the OPTN received questions from the transplant community as to whether certain clinical procedures would be considered VCA transplants. This clarification of VCA-specific policies and bylaws addresses concerns regarding compliance with the Final Rule and answers questions raised by the transplant community.

Summary of Changes

- Restructured the VCA definition to clarify that OPTN Policy does not narrow or expand the federal definition of VCA as established in the Final Rule[3]
- Retained the nine criteria established in the Final Rule under a general definition of VCA
- Created the term "covered VCAs" and used this term to refer to the body parts identified and regulated by the OPTN
- Moved list of covered body parts under a new definition for "covered VCAs"
- Made the list of covered body parts exclusive (removed "including, but not limited to" language)
- Clarified that only vascularized gland transplants are considered VCA transplants

Implementation

No action is required from members. There are no impacts in UNet^{SM} for system users, and no change in how transplant programs register VCA candidates for the waiting list.

Affected Policy and Bylaws Language

New language is underlined (example) and language that is deleted is struck through (~~example~~).

OPTN Policies

1.2 Definitions

The definitions that follow are used to define terms specific to the OPTN Policies.

C

Covered Vascularized Composite Allograft body parts (covered VCAs)

[2] 42 CFR §121.4 (e)(3).
[3] 42 CFR §121.2.

The body parts listed below are covered VCAs. Covered VCAs are categorized by type as follows:

Covered VCA(s)	Type:
Any group of vascularized body parts from the upper limb	Upper limb
Face, larynx, vascularized parathyroid gland, scalp, trachea, vascularized thyroid, and any other vascularized body parts from the head and neck	Head and neck
Abdominal wall, symphysis pubis, and any group of vascularized skeletal elements of the pelvis	Abdominal wall
Uterus, internal and external male and female genitalia, and urinary bladder	Genitourinary organ
Adrenal and thymus	Vascularized gland
Pelvic structures that are attached to the lower limb and transplanted intact, gluteal region, vascularized bone transfers from the lower extremity, toe transfers, and any group of vascularized body parts from the lower limb	Lower limb
Spine axis, chest wall, and other composite graft of vascularized muscle, bone, nerve, or skin	Musculoskeletal composite graft segment
Spleen	Spleen

O

Organ allocation policies

OPTN Policies: *Policy 6: Allocation of Hearts and Heart-Lungs, Policy 7: Allocation of Intestines, Policy 8: Allocation of Kidneys, Policy 9: Allocation of Livers and Liver-Intestines, Policy 10: Allocation of Lungs, and Policy 11: Allocation of Pancreas, Kidney-Pancreas, and Islets,* and *Policy 12: Allocation of Covered Vascularized Composite Allografts.*

V

Vascularized Composite Allograft (VCA)

~~A transplant involving any body parts that meet~~A body part meeting *all* nine of the following criteria:

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.
9. Susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.

Refer to "Covered Vascularized Composite Allograft body parts (covered VCAs)" for the list of body parts covered by OPTN Policies and Bylaws.

~~The following body parts are considered VCAs:~~

- ~~Upper limb (including, but not limited to, any group of body parts from the upper limb or radial forearm flap)~~
- ~~Head and neck (including, but not limited to, face including underlying skeleton and muscle, larynx, parathyroid gland, scalp, trachea, or thyroid)~~
- ~~Abdominal wall (including, but not limited to, symphysis pubis or other vascularized skeletal elements of the pelvis)~~
- ~~Genitourinary organs (including, but not limited to, uterus, internal/external male and female genitalia, or urinary bladder)~~
- ~~Glands (including, but not limited to adrenal or thymus)~~
- ~~Lower limb (including, but not limited to, pelvic structures that are attached to the lower limb and transplanted intact, gluteal region, vascularized bone transfers from the lower extremity, anterior lateral thigh flaps, or toe transfers)~~
- ~~Musculoskeletal composite graft segment (including, but not limited to, latissimus dorsi, spine axis, or any other vascularized muscle, bone, nerve, or skin flap)~~
- ~~Spleen~~

2.2 OPO Responsibilities

The host OPO is responsible for *all* of the following:

1. Identifying potential deceased donors.
2. Providing evidence of authorization for donation.
3. Evaluating deceased donors.
4. Maintaining documentation used to exclude any patient from the imminent neurological death data definition or the eligible data definition.
5. Verifying that death is pronounced according to applicable laws.
6. Establishing and then implementing a plan to address organ donation for diverse cultures and ethnic

populations.

7. Ensuring the clinical management of the deceased donor.
8. Ensuring that the necessary tissue-typing material is procured, divided, and packaged.
9. Assessing deceased donor organ quality.
10. Preserving, labeling, packaging, and transporting the organs. Labeling and packaging must be completed using the OPTN organ tracking system according to *Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage*.
11. Executing the match run and using the resulting match for each deceased donor organ allocation. The previous sentence does not apply to covered VCA transplants; instead, members must allocate covered VCAs according to *Policy 12.2: Covered VCA Allocation*.
12. Documenting and maintaining complete deceased donor information for seven years for all organs procured.
13. Ensuring that all deceased donor information, according to *Policy 2.11: Required Deceased Donor Information,* is reported to the OPTN upon receipt to enable complete and accurate evaluation of donor suitability by transplant programs.
14. Ensuring that documentation for *all* of the following deceased donor information is submitted to the OPTN upon receipt:
    a. ABO source documentation
    b. ABO subtype source documentation
    c. Infectious disease results source documentation
    d. Death pronouncement source documentation
    e. Authorization for donation source documentation
    f. HLA typing source documentation

15. Maintaining blood specimens appropriate for serologic and nucleic acid testing (NAT), as available, for each deceased donor for at least 10 years after the date of organ transplant, and ensuring these samples are available for retrospective testing. The samples must be collected within 24 hours prior to organ procurement. The host OPO must document the type of sample in the deceased donor medical record and, if possible, should use qualified specimens.

2.14.E Deceased Donor Authorization Requirement

The host OPO may only recover organs that it has received authorization to recover. An authorized organ should be recovered if it is transplantable or a potential transplant recipient is identified for the organ. If an authorized organ is not recovered, the host OPO must document the specific reason for non-recovery.

Extra vessels may only be recovered with at least one organ. To recover and use extra vessels in an organ transplant, the deceased donor authorization forms must include language indicating that the extra vessels will be used for transplant.

Recovery of covered ~~vascularized composite allografts (~~VCAs~~)~~ for transplant must be specifically authorized from individuals authorizing donation, whether that be the donor or a surrogate donation decision-maker consistent with applicable state law. The specific authorization for covered VCAs must be documented by the host OPO.

5.4.B Order of Allocation

The process to allocate deceased donor organs occurs with these steps:

1. The match system eliminates candidates who cannot accept the deceased donor based on size or blood type.
2. The match system ranks candidates according to the allocation sequences in the organ allocation policies.
3. OPOs must first offer organs to potential transplant recipients (PTRs) in the order that the PTRs appear on a match run.
4. If no transplant program on the initial match run accepts the organ, the host OPO may give transplant programs the opportunity to update candidates' data with the OPTN. The host OPO must re-execute the match run to allocate the organ.
5. Extra vessels allocated with an organ but not required for its transplant can be shared according to *Policy 16.6.A: Extra Vessels Use and Sharing*.
6. Members may export deceased donor organs to hospitals in foreign countries only after offering these organs to all PTRs on the match run. Members must submit the *Organ Export Verification Form* to the OPTN prior to exporting deceased donor organs.

This policy does not apply to covered VCA transplants; instead, members must allocate covered VCAs according to *Policy 12.2: Covered VCA Allocation*.

5.6.A Receiving and Reviewing Organ Offers

Transplant hospitals must view organ offers and respond to these offers through the match system. The previous sentence does not apply to covered VCA transplants.

The transplanting surgeon at the receiving transplant hospital is responsible for ensuring the medical suitability of organs offered for transplant to potential recipients, including whether deceased donor and candidate blood types (and donor subtype, when used for allocation) are compatible or intended incompatible.

5.6.B Time Limit for Review and Acceptance of Organ Offers

This policy does not apply to expedited liver offers as outlined in *Policy 9.10.B: Expedited Liver Offers.*

A transplant hospital has a total of one hour after receiving the initial organ offer notification to access the deceased donor information and submit a provisional yes or an organ offer refusal.

Once the host OPO has provided all the required deceased donor information according to *Policy 2.11: Required Deceased Donor Information*, with the exception of organ anatomy and recovery information, the transplant hospital for the initial primary potential transplant recipient must respond to the host OPO within one hour with *either* of the following:

- An organ offer acceptance
- An organ offer refusal

All other transplant hospitals who have entered a provisional yes must respond to the host OPO within 30 minutes of receiving notification that their offer is for the primary potential transplant recipient with *either* of the following:

- An organ offer acceptance
- An organ offer refusal

The transplant hospital must respond as required by these timeframes or it is permissible for the host OPO to offer the organ to the transplant hospital for the candidate that appears next on the match run.

This policy does not apply to covered VCA transplants.

Policy 12: Allocation of Covered Vascularized Composite Allografts ~~(VCA)~~

12.1 Waiting Time

Waiting time for ~~VCA~~ candidates registered for a covered VCA begins when the candidate is registered on the waiting list. Candidates are registered by covered VCA type: upper limb, head and neck, abdominal wall, genitourinary organ, vascularized gland, lower limb, musculoskeletal composite graft segment, or spleen. ~~For those candidates registered prior to September 1, 2014, waiting time will begin when the transplant hospital requests that the OPO actively seek a donor for an identified VCA candidate.~~

12.2 Covered VCA Allocation

A covered VCA~~s~~ from a deceased donor~~s~~ is~~are~~ allocated to candidates registered for that covered VCA ~~in need of that VCA~~ according to *Table 12-1* below.

Table 12-1: Allocation of Covered VCAs from Deceased Donors

Classification	Candidates that are registered for the covered VCA at a transplant hospital that is within this distance from a donor hospital:	And are:
1	500 NM	Blood type compatible with the donor
2	Nation	Blood type compatible with the donor

Within each classification, candidates are sorted by waiting time (longest to shortest).

When a covered VCA is allocated, the host OPO must document *both* of the following:

1. How the organ is allocated and the rationale for allocation.
2. Any reason for organ offer refusals.

14.5.C Reporting of Living Donor Blood Type and Subtype

The recovery hospital must report and verify the living donor blood type prior to registration with the OPTN using the *Living Donor Feedback Form* as required below:

1. Two different qualified health care professionals, as defined in the recovery hospital's protocol, must each make an independent report to the OPTN for blood type. For covered VCA recoveries, the blood type verification and reporting must be recorded in the living donor's medical record.
2. If blood subtype is used for ensuring transplant compatibility or allocation, a qualified health care professional must report blood subtype to the OPTN. This report must be verified by a different qualified health care professional according to the recovery hospital's protocol. For covered VCA recoveries, the blood subtype verification and reporting must be recorded in the living donor's medical record.
3. Both qualified health care professionals must use all known available blood type and subtype determination source documents to verify they:
    a. Contain blood type and subtype (if used for ensuring transplant compatibility or allocation) results for the donor
    b. Indicate the same blood type and subtype (if used for ensuring transplant compatibility or allocation) on the test results. If the results are conflicting or indeterminate, the recovery hospital must refer to their written protocol as outlined in *Policy 14.5.A: Living Donor Blood Type Determination*.
    c. Match the result reported to the OPTN or VCA donor medical record

The recovery hospital must document that reporting was completed according to the hospital's protocol and the above requirements.

15.4.A Host OPO Requirements for Reporting Post-Procurement Donor Results and Discovery of Potential Disease Transmissions

The host OPO must report all positive test results and other relevant information received post-procurement for each donor as soon as possible but no later than 24 hours after receipt as follows:

1. All results indicating Pathogens of Special Interest must be reported to the receiving transplant program's patient safety contact and the OPTN Improving Patient Safety Portal. The OPTN Contractor provides a list of Pathogens of Special Interest, including any results that can be excluded from reporting. The OPTN Contractor reviews and updates this list at least annually.
2. All other positive test results and relevant information must be reported according to *Table 15-2 below.*

Table 15-2: Host OPO Reporting Requirements for Positive Post-Procurement Donor Results and Discovery of Potential Disease Transmissions

	The host OPO must report *all* of the following *positive* results:	To:
Samples relevant to all recipients	Serologic, NAT, or antigen results indicating presence of parasites, virus, or fungi	The receiving transplant program's patient safety contact
	Cultures from the following specimens: • Ascites • Blood • Cerebrospinal fluid (CSF) • Deep wound • Genital • Pericardial • Pleural fluid	The receiving transplant program's patient safety contact
	Mycobacterial smears and cultures	The receiving transplant program's patient safety contact
	Fungal smears and cultures with the exception of *Candida* species	The receiving transplant program's patient safety contact
Relevant information	Respiratory samples (bacterial or *Candida species*) *only* to transplant programs receiving lungs or <u>covered</u> head and neck VCAs	The receiving transplant program's patient safety contact
	Urine cultures *(*bacterial or *Candida species) only* to transplant programs receiving kidneys or <u>covered</u> genitourinary <u>organ</u> VCAs	The receiving transplant program's patient safety contact
	Malignancy or other findings highly suggestive of malignancy recognized after procurement	1. The receiving transplant program's patient safety contact 2. The OPTN Improving Patient Safety Portal
	Histopathology results reported post-procurement	The receiving transplant program's patient safety contact
	All *final* culture information for any culture results that were reported according to these requirements	The receiving transplant program's patient safety contact
	Other psycho-social history, medical history, autopsy, testing, and laboratory findings identifying infectious conditions that may adversely affect a potential transplant recipient	The receiving transplant program's patient safety contact

18.1 Data Submission Requirements

Members must report accurate data to the OPTN using standardized forms according to *Table 18-1* below. Members are responsible for providing documentation upon request to verify the accuracy of all data that is submitted to the OPTN through the use of standardized forms.

Table 18-1: Data Submission Requirements

The following member:	Must submit the following materials to the OPTN:	Within:	For:
Histocompatibility Laboratory	*Donor histocompatibility* (DHS)	30 days after the OPO submits the deceased donor registration	Each heart, intestine, kidney, liver, lung, or pancreas donor typed by the laboratory
Histocompatibility Laboratory	*Recipient histocompatibility* (RHS)	*Either* of the following: • 30 days after the transplant hospital removes the candidate from the waiting list because of transplant • 30 days after the transplant hospital submits the *recipient feedback*	Each heart, intestine, kidney, liver, lung, or pancreas transplant recipient typed by the laboratory
OPOs, all	*Death notification records* (DNR)	30 days after the end of the month in which a donor hospital reports a death to the OPO or the OPO identifies the death through a death record review	All imminent neurological deaths and eligible deaths in its DSA
OPOs, all	*Monthly Donation Data Report: Reported Deaths*	30 days after the end of the month in which a donor hospital reports a death to the OPO	All deaths reported by a hospital to the OPO
Allocating OPO	*Potential transplant recipient* (PTR)	30 days after the match run date by the OPO or the OPTN	Each deceased donor heart, intestine, kidney, liver, lung, or pancreas that is offered to a potential recipient
Allocating OPO	*VCA Candidate List*	30 days after the procurement date	Each covered deceased donor VCA organ that is offered to a potential covered VCA recipient

The following member:	Must submit the following materials to the OPTN:	Within:	For:
Host OPO	*Donor organ disposition (feedback)*	5 business days after the procurement date	Individuals, except living donors, from whom at least one organ is recovered
Host OPO	*Deceased donor registration* (DDR)	30 days after the *donor organ disposition (feedback)* form is submitted and disposition is reported for all organs	All deceased donors
Recovery Hospitals	*Living donor feedback*	The time prior to donation surgery	Each potential living donor organ recovered at the hospital This does not apply to covered VCA donor organs
Recovery Hospitals	*Living donor feedback* Members must amend the form or contact the OPTN Contractor to amend this form according to *Policy 18.6: Reporting of Living Donor Adverse Events*	72 hours after the donor organ recovery procedure	Any potential living donor who received anesthesia but did not donate an organ or whose organ is recovered but not transplanted into any recipient
Recovery Hospitals	*Living donor registration* (LDR)	60 days after the recovery hospital submits the *living donor feedback* form	Each living donor organ recovered at the hospital This does not apply to covered VCA donor organs

The following member:	Must submit the following materials to the OPTN:	Within:	For:
Recovery Hospitals	*Living donor follow-up* (LDF)	60 days after the six-month, 1-year, and 2-year anniversary of the donation date	Each living donor organ recovered at the hospital This does not apply to covered VCA, domino donor, and non-domino therapeutic donor organs.
Transplant hospitals	*Organ specific transplant recipient follow-up* (TRF)	*Either* of the following: • 30 days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure • 14 days from notification of the recipient's death or graft failure	Each recipient followed by the hospital
Transplant hospitals	*Organ specific transplant recipient registration* (TRR)	60 days after transplant hospital removes the recipient from the waiting list	Each recipient transplanted by the hospital
Transplant hospitals	*Liver Post-Transplant Explant Pathology*	60 days after transplant hospital submits the *recipient feedback* form	Each liver recipient transplanted by the hospital
Transplant hospitals	*Recipient feedback*	1 day after the transplant	Each heart, intestine, kidney, liver, lung, or pancreas recipient transplanted by the hospital
Transplant hospitals	*Candidate Removal Worksheet*	1 day after the transplant	Each covered VCA recipient transplanted by the hospital

The following member:	Must submit the following materials to the OPTN:	Within:	For:
Transplant hospitals	*Recipient malignancy* (PTM)	30 days after the transplant hospital reports the malignancy on the *transplant recipient follow-up* form	Each heart, intestine, kidney, liver, lung, or pancreas recipient with a reported malignancy that is followed by the hospital.
Transplant hospitals	*Transplant candidate registration* (TCR)	30 days after the transplant hospital registers the candidate on the waiting list	Each heart, intestine, kidney, liver, lung, or pancreas candidate on the waiting list or recipient transplanted by the hospital

18.2 Timely Collection of Data

Members must collect and submit timely information to the OPTN. Timely data on recipients and living donors is based on recipient or living donor status at a time as close as possible to the specified transplant event anniversary. *Table 18-2: Timely Data Collection* sets standards for when the member must collect the data from the patient.

Table 18-2: Timely Data Collection

Information is timely if this Member:	Collects this information for this form:	Within this time period:
Transplant hospital	*Organ specific transplant recipient registration* (TRR)	When the transplant recipient is discharged from the hospital or 42 days following the transplant date, whichever is first
Recovery hospital	*Living donor registration* (LDR)	When the living donor is discharged from the hospital or 42 days following the transplant date, whichever is first This does not apply to covered VCA transplants.
Recovery hospital	*Living donor follow-up* (LDF)	60 days before or after the six-month, 1-year, and 2-year anniversary of the donation date or This does not apply to covered VCA transplants.

18.3 Recording and Reporting the Outcomes of Organ Offers

The allocating OPO and the transplant hospitals that received organ offers share responsibility for reporting the outcomes of all organ offers. OPOs are responsible for reporting the outcomes of organ offers to the OPTN within 30 days of the match run date. OPOs, transplant hospitals, and the OPTN may report this information. The OPO or the OPTN must obtain PTR refusal codes directly from the physician, surgeon, or their designee involved with the potential recipient and not from other personnel.

If the OPO reports the refusal code, then the transplant hospital has 45 days from the match run date, to validate the refusal code by either confirming or amending the refusal code. If the OPO and transplant hospital report different refusal codes, then the OPTN will use the transplant hospital's refusal code for data analysis purposes.

If the OPTN reports the refusal code, then the transplant hospital will not be required to validate the refusal code.

This policy does not apply to covered VCA organ offers; instead, members must document covered VCA offers according to *Policy 18.1: Data Submission Requirements*.

OPTN Bylaws

Appendix J: Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs

This appendix describes the information and documentation transplant hospitals must provide when:

- Submitting a completed membership application to apply for approval for each designated VCA transplant program.
- Completing a Personnel Change Application for a change in key personnel at each designated VCA transplant program.

There are eight types of VCA transplant programs: upper limb, head and neck, abdominal wall, genitourinary organ, vascularized gland, lower limb, musculoskeletal composite graft segment, and spleen. For approval as a designated VCA transplant program, transplant hospitals must also:

1. Meet general membership requirements, which are described in *Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs*.
2. Have approval for at least one designated transplant program in addition to the vascularized composite allograft program designation.

For more information on the application and review process, see *Appendix A: Membership Application and Review*.

A. Additional Primary Surgeon Requirements for Upper Limb Transplant Programs

In addition to the requirements as described in *Section J.2* above, the surgeon for an upper limb transplant program must meet *both* of the following:

1. Have current certification by the American Board of Plastic Surgery, the American Board of Orthopedic Surgery, the American Board of Surgery, or the Royal College of Physicians and Surgeons of Canada. In the case of a surgeon who has just completed training and whose board certification is pending, the Membership and Professional Standards Committee (MPSC) may grant conditional approval for 24 months to allow time for the surgeon to complete board certification, with the possibility of one additional 16-month extension.

   In place of current certification by the American Board of Plastic Surgery, the American Board of Orthopedic Surgery, the American Board of Surgery, the Royal College of Physicians and Surgeons of Canada, or a pending certification, the surgeon must demonstrate the following experience:
   a. Acted as the first-assistant or primary surgeon on at least 1 covered VCA procurement.
   b. Participated in the pre-operative evaluation of at least 3 potential upper limb transplant patients.
   c. Acted as primary surgeon of a least 1 upper limb transplant.
   d. Participated in the post-operative follow-up of at least 1 upper limb recipient for 1 year post-transplant.

   The upper limb procurement experience must be documented in a log that includes the Donor ID or other unique identifier that can be verified by the OPTN Contractor. The experience for upper limb transplant procedures must be documented in a log that includes the dates of procedures and evaluations, the role of the surgeon, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained.

   In addition to experience above, a surgeon without current or pending certification by the American Board of Plastic Surgery, the American Board of Orthopedic Surgery, the American Board of Surgery, or the Royal College of Physicians and Surgeons of Canada must also:
   a. Be ineligible for American board certification.
   b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the surgeon obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
   c. Provide to the OPTN Contractor two letters of recommendation from directors of designated VCA transplant programs not employed by the applying hospital. These letters must address:
      i. Why an exception is reasonable.

ii. The surgeon's overall qualifications to act as a primary upper limb transplant surgeon.
iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
iv. Any other matters judged appropriate.

If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws. If the OPTN Contractor becomes aware that a primary surgeon has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws.

B. Additional Primary Surgeon Requirements for Head and Neck Transplant Programs

In addition to the requirements as described in section J.2 above, the transplant surgeon for a head and neck transplant program must meet *both* of the following:

1. Have current certification by the American Board of Plastic Surgery, the American Board of Otolaryngology, American Board of Oral and Maxillofacial Surgery, the American Board of Surgery, or the Royal College of Physicians and Surgeons of Canada. In the case of a surgeon who has just completed training and whose board certification is pending, the Membership and Professional Standards Committee (MPSC) may grant conditional approval for 24 months to allow time for the surgeon to complete board certification, with the possibility of one additional 16-month extension.

   In place of current certification by the American Board of Plastic Surgery, the American Board of Otolaryngology, the American Board of Oral and Maxillofacial Surgery the American Board of Surgery, the Royal College of Physicians and Surgeons of Canada, or a pending certification, the surgeon must demonstrate the following experience:
   a. Acted as the first-assistant or primary surgeon on at least 1 covered VCA procurement.
   b. Participated in the pre-operative evaluation of at least 3 potential head and neck transplant patients.
   c. Acted as primary surgeon of a least 1 head and neck transplant.
   d. Participated in the post-operative follow-up of at least 1 head and neck recipient for 1 year post-transplant.

   The head and neck procurement experience must be documented in a log that includes the Donor ID or other unique identifier that can be verified by the OPTN Contractor. The experience for head and neck transplant procedures must be documented in a log that includes the dates of procedures and evaluations, the role of the surgeon, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This

log must be signed by the program director, division chief, or department chair where the experience was gained.

In addition to experience above, a surgeon without current or pending certification by the American Board of Plastic Surgery, the American Board of Otolaryngology, the American Board of Oral and Maxillofacial Surgery, the American Board of Surgery, or the Royal College of Physicians and Surgeons of Canada must also:

a. Be ineligible for American board certification.
b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the surgeon obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
c. Provide to the OPTN Contractor two letters of recommendation from directors of designated VCA transplant programs not employed by the applying hospital. These letters must address:
    i. Why an exception is reasonable.
    ii. The surgeon's overall qualifications to act as a primary head and neck transplant surgeon.
    iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
    iv. Any other matters judged appropriate.

If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws. If the OPTN Contractor becomes aware that a primary surgeon has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws.

D. Additional Primary Surgeon Requirements for Other VCA Transplant Programs

This pathway is only for the primary transplant surgeon at a VCA transplant program intending to transplant covered VCA body parts other than those that will be transplanted at approved upper limb, head and neck, or abdominal wall transplant programs. The VCA transplant program must specify the types of body parts it will transplant in the application from the following options: genitourinary organ, vascularized gland, lower limb, musculoskeletal composite graft segment, or spleen. In addition to the requirements as described in section J.2 above, the primary surgeon for other VCA transplant programs must meet *all* of the following:

~~1. Specify to the OPTN Contractor the types of VCA transplant the surgeon will perform: according to *OPTN Policy 1.2: Administrative Rules and Definitions, Vascularized Composite Allograft*.~~

~~2.~~ 1. Have current American Board of Medical Specialties or Royal College of Physicians and Surgeons of Canada certification in a specialty relevant to the type of VCA transplant the surgeon will be performing.

In place of current certification by the American Board of Medical Specialties or the Royal College of Physicians and Surgeons of Canada, the surgeon must:

a. Be ineligible for American board certification.
b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the surgeon obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
c. Provide to the OPTN Contractor two letters of recommendation from directors of designated VCA transplant programs not employed by the applying hospital. These letters must address:
    i. Why an exception is reasonable.
    ii. The surgeon's overall qualifications to act as a primary VCA transplant surgeon.
    iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
    iv. Any other matters judged appropriate.

If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws. If the OPTN Contractor becomes aware that a primary surgeon has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws.

~~3.~~ 2. Have performed the pre-operative evaluation of at least 3 potential covered VCA transplant patients.

~~4.~~ 3. Have current working knowledge in the surgical specialty, defined as independent practice in the specialty over a consecutive five-year period.

~~5.~~ 4. Have assembled a multidisciplinary surgical team that includes specialists necessary to complete the VCA transplant including, for example, plastic surgery, orthopedics,

otolaryngology, obstetrics and gynecology, urology, or general surgery. This team must include a team member that has microvascular experience such as replantation, revascularization, free tissue transfer, and major flap surgery. These procedures must be documented in a log that includes the dates of procedures, the role of the surgeon, and the medical record number, or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained. The team must have demonstrated detailed planning that is specific for the types of VCA transplant the program will perform.

A letter from the presiding executive of the transplant hospital where the VCA transplant will be performed must provide written verification that requirements 1 through ~~5~~4 above have been met by the primary surgeon.

Appendix M: Definitions

C

Covered Vascularized Composite Allograft body parts (covered VCAs)
The body parts listed below are covered VCAs. Covered VCAs are categorized by type as follows:

Covered VCA(s)	Type:
Any group of vascularized body parts from the upper limb	Upper limb
Face, larynx, vascularized parathyroid gland, scalp, trachea, vascularized thyroid, and any other vascularized body parts from the head and neck	Head and neck
Abdominal wall, symphysis pubis, and any group of vascularized skeletal elements of the pelvis	Abdominal wall
Uterus, internal and external male and female genitalia, and urinary bladder	Genitourinary organ
Adrenal and thymus	Vascularized gland
Pelvic structures that are attached to the lower limb and transplanted intact, gluteal region, vascularized bone transfers from the lower extremity, toe transfers, and any group of vascularized body parts from the lower limb	Lower limb
Spine axis, chest wall, and other composite graft of vascularized muscle, bone, nerve, or skin	Musculoskeletal composite graft segment
Spleen	Spleen

D

Designated Transplant Program

An organ-specific program that has been approved by the OPTN~~MPSC to~~ as part of the transplant hospital membership. A transplant hospital member may have transplant programs for transplantation of hearts, lungs, liver, kidneys, pancreas, pancreas islets, intestines, ~~and vascularized composite allografts~~ upper limbs, head and neck VCAs, abdominal walls, genitourinary organs, vascularized glands, lower limbs, musculoskeletal composite graft segments, and spleens. In order to be a transplant hospital member, the transplant hospital must have current designated transplant program approval for at least one organ. A designated transplant program may also be called a transplant program in these Bylaws.

V

Vascularized Composite Allograft (VCA)

~~A transplant involving any body parts that meets~~A body part meeting *all* nine of the following criteria:

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.
9. Susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.

~~For the list of covered VCA body parts designated by the OPTN as VCAs, see Vascularized Composite Allograft (VCA) in OPTN *Policy 1.2: Definitions*.~~ Refer to "Covered Vascularized Composite Allograft body parts (covered VCAs)" for the list of body parts covered by OPTN Policies and Bylaws.