OPTN

Notice of OPTN Policy and Bylaw Changes

Vascularized Composite Allograft Membership Changes

Sponsoring Committee:	**Vascularized Composite Allograft Transplantation**
Policy and Bylaws Affected:	***Bylaw Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs*** ***Bylaw Appendix J: Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs*** ***Bylaw Appendix M: Definitions*** ***Policy 1.2: Definitions***
Public Comment:	**January 27, 2015 – March 27, 2015** **January 25, 2016 – March 25, 2016** **January 22, 2018 – March 23, 2018**
Board Approved:	**June 1, 2015** **June 6, 2016** **June 12, 2018**
Effective Date:	**Pending implementation and notice to OPTN members**

Introduction

Because three separate actions related to VCA transplant program membership requirements were passed at different times by the OPTN Board of Directors, this notice consolidates the three sets of actions to clarify the changes that will go into effect pending implementation and notice.

Purpose of Policy and Bylaw Changes

Current OPTN Bylaws do not include specific training and experience requirements for key personnel at vascularized composite allograft (VCA) transplant programs. This proposal establishes minimal certification, training, and experience for individuals serving as primary transplant physicians and surgeons at VCA transplant programs.

Furthermore, while the OPTN Final Rule requires the OPTN to identify all covered body parts in any policies specific to VCA transplants, current OPTN Bylaws and Policies do not consistently specify these covered body parts. This Board-approved action adds the list of covered body parts to OPTN Bylaws and Policies in order to meet the requirements of the Final Rule.

Finally, in December 2015, the Board approved changes to the OPTN Bylaws to remove the term “foreign equivalent” from transplant program key personnel qualification requirements. These changes did not apply to the requirements for key personnel at VCA transplant programs, resulting in two different standards. This Board-approved action provides options for non-board certified or U.S. board ineligible individuals applying for key personnel positions at VCA transplant programs.

Proposal History

This notice of OPTN Policy and Bylaw changes is a summary of changes that were approved by the OPTN Board between 2015 to 2018 but have not yet been implemented. The purpose of this summary is to compile all of those changes in one place, as the OPTN plans to implement these changes together in 2021. Some of the policy notices include changes to policies and bylaws that have not yet been implemented by the OPTN. The original policy notices are listed below:

- Membership Requirements for VCA Transplant Programs, approved June 1, 2015
  - This proposal would have established a clinical experience pathway for non-board certified personnel. This pathway would have expired on September 1, 2018.
- List Covered Body Parts Pertaining to VCA, approved June 6, 2016
- Remove Clinical Experience Pathway for Non-board Certified Key Personnel at Head and Neck, and Upper Limb Transplant Programs, approved June 6, 2016
  - This proposal would have removed the clinical experience pathway for non-board certified personnel effective on September 1, 2018.
- Align VCA Transplant Program Membership Requirements with Requirements of Other Solid Organ Transplant Programs (Part 1), approved June 12, 2018
  - This proposal updated the pathway for non-board certified individuals to require continuing medical education in addition to clinical experience.
- Align VCA Transplant Program Membership Requirements with Requirements of Other Solid Organ Transplant Programs (Part 2), approved June 12, 2018
  - This proposal restored the clinical experience pathway but removed the expiration date of September 1, 2018, so that the clinical experience pathway would remain in effect until the updated pathway described above could be implemented.

Summary of Changes

Changes to OPTN Bylaws Appendix J establish abdominal wall, head and neck, upper limb, and other VCA transplant programs and specify requirements for program directors, primary transplant surgeons, and primary transplant physicians at these programs. The Bylaws outline key personnel certification, training, and experience requirements. Other changes to OPTN Bylaws and Policies include:

- Adding the list of eight Covered Body Parts that are VCAs to OPTN Policy 1.2
- Including the general requirements for transplant hospitals applying for a VCA transplant program, and multidisciplinary transplant exposure for the primary transplant surgeon for other VCA transplant programs
- Providing options for non-board certified or U.S. board ineligible individuals applying for key personnel positions at VCA transplant programs, including the option to qualify under a CME pathway. The changes are consistent with options available to applicants for key personnel positions at other organ transplant programs.

Implementation

The approved membership requirements for VCA Transplant Programs represent a significant change from the previous membership requirements. At the time of implementation, all key personnel at VCA transplant programs in the U.S. will be required to reapply to the OPTN. UNOS will send a 30-day notice to all currently approved VCA transplant programs that new applications will be coming and must be completed. Once applications are sent to members, VCA transplant programs will need to indicate their

desire to “opt out”, or will need to submit a completed application within 120 days. Transplant hospitals with approved VCA transplant programs will be responsible for proposing individuals who will qualify for key personnel positions. If these key personnel are U.S. board ineligible, these individuals will be responsible for adhering to the requirements of the CME pathway identified in their application.

Affected Policy Language

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

OPTN Bylaws
Appendix D:
Membership Requirements for Transplant Hospitals and Transplant Programs

A transplant hospital member is any hospital that performs organ transplants and has current approval as a designated transplant program for at least one organ.

~~The following provisions of Appendix D do not apply to VCA transplant programs:~~

- ~~*D.5: Transplant Program Director*~~
- ~~*D.6: Transplant Program Key Personnel*~~
- ~~*D.7: Changes in Key Transplant Program Personnel*~~[1]

D.3 Designated Transplant Program Requirement

In order to receive organs for transplantation, a transplant hospital member must have current approval as a designated transplant program for at least one organ. A transplant hospital can only have one designated transplant program for each respective organ. Designated transplant programs must meet at least *one* of the following requirements:

- Have approval as a transplant program by the Secretary of the U.S. Department of Health and Human Services (HHS) for reimbursement under Medicare.
- Have approval as a transplant program in a Department of Veterans Affairs, Department of Defense, or other Federal hospital.

[1] Due to subsequent renumbering since this Bylaw change was approved by the OPTN Board of Directors in 2015, these provisions of Appendix D are now D.6, D.7, and D.8. The VCA exclusion is now stricken. When these changes go into effect, VCA programs must comply with provisions for the Transplant Program Director, Transplant Program Key Personnel, and Changes in Key Transplant Program Personnel.

- Qualify as a designated transplant program according to the membership requirements of these Bylaws.

  The OPTN does not grant designated transplant program approval for any type of vascularized organ transplantation for which the OPTN has not established specific criteria. In order to perform vascularized organ transplantation procedures for which there are no OPTN-established criteria, including multi-visceral transplants, a hospital must be a transplant hospital member and have current approval as a designated transplant program for at least one of the organ types involved in multi-visceral transplant. In the case of abdominal multi-visceral organ transplants, the transplant hospital must have approval as a designated liver transplant program. ~~In the case of vascularized composite allografts (including, but not limited to, faces and upper extremities), the transplant hospital must have approval for at least one designated transplant program in addition to the vascularized composite allograft program designation.~~

D.7 Transplant Program Key Personnel

Designated transplant programs must have certain key personnel on site according to Table D-1 below.[2]

D-1: Key Personnel Requirements for Designated Transplant Programs

Designated transplant program type:	Required key personnel:
Kidney, liver, heart, lung, pancreas, or vascularized composite allograft (VCA)	Primary surgeon and primary physician
Islet	Clinical leader

For the detailed primary surgeon, primary physician, or clinical leader requirements for specific transplant programs, see the following appendices of these Bylaws:

- *Appendix E:Membership and Personnel Requirements for Kidney Transplant Programs*
- *Appendix F: Membership and Personnel Requirements for Liver Transplant Programs*
- *Appendix G: Membership and Personnel Requirements for Pancreas Transplant Programs*
- *Appendix H: Membership and Personnel Requirements for Heart Transplant Programs*
- *Appendix I: Membership and Personnel Requirements for Lung Transplant Programs*
- *Appendix J: Membership and Personnel Requirements for Vascularized Composite Allograft Transplant Programs*
- *Appendix K: Membership and Personnel Requirements for Islet Transplant Programs*

[2] Table D-1 was approved by the OPTN Board of Directors in December 2018. See notice available at https://optn.transplant.hrsa.gov/media/2790/pancreas_policynotice_islet_201901.pdf

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

This appendix describes the information and documentation transplant hospitals must provide when ~~requesting approval as a designated VCA transplant program. VCAs include, but are not limited to, faces and upper extremities.~~:

- 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.

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*.

~~J.1 Letter of Notification~~

~~If a transplant hospital member commits to performing VCA transplants the hospital must send a written notification to the OPTN Contractor that includes *both* of the following:~~

~~1. The specific type or types of VCA transplant the hospital will perform.~~
~~2. If the member will perform deceased donor VCA transplants, assurance from the local OPO that it will provide the same type or types of VCA for transplantation.~~

~~The letter of notification from the transplant hospital must be signed by *all* of the following individuals:~~

~~1. The chief administrative officer for the institution.~~
~~2. The reconstructive surgeon for each type of VCA transplant with expertise in microsurgical reconstruction, prior experience in VCA, or in lieu of actual VCA experience, extensive experience in the applicable reconstructive procedure as required, such as hand replantation or facial reconstruction.~~
~~3. The transplant physician or transplant surgeon for each type of VCA transplant at an approved transplant program that has completed an approved transplant fellowship, or qualifies by documented transplant experience, in a medical or surgical specialty.~~

~~The OPTN Contractor will then notify the transplant hospital member of the program designation for each type of VCA transplant.~~

J.1 Program Director, Primary Transplant Surgeon, and Primary Transplant Physician

A VCA transplant program must identify at least one designated staff member to act as the VCA program director. The director must be a physician or surgeon who is a member of the transplant hospital staff. The same individual can serve as the program director for multiple VCA programs.

The program must also identify a qualified primary transplant surgeon and primary transplant physician, as described below. The primary transplant surgeon, primary transplant physician, and VCA program director for each designated VCA transplant program must submit a detailed Program Coverage Plan to the OPTN Contractor. For information about the Program Coverage Plan, see *Section D.7.B: Surgeon and Physician Coverage* (Program Coverage Plan).

J.2 Primary VCA Transplant Surgeon Requirements

A designated VCA transplant program must have a primary transplant surgeon that meets *all* of the following requirements:

1. The surgeon must have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The surgeon must be accepted onto the hospital's medical staff, and be on-site at this hospital.
3. The surgeon must have documentation from the hospital's credentialing committee that it has verified the surgeon's state license, training, and continuing medical education, and that the surgeon is currently a member in good standing of the hospital's medical staff.
4. The surgeon must have observed at least 2 multi-organ procurements. These observations must be documented in a log that includes the date of procurement and Donor ID.

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 VCA procurement.
b. Participated in the pre-operative evaluation of at least 3 potential upper limb transplant patients.
c. Acted as primary surgeon of at 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.

2. Completion of at least *one* of the following:
   a. Any Accreditation Council of Graduate Medical Education (ACGME) approved fellowship program in hand surgery.
   b. A fellowship program in hand surgery that meets *all* of the following criteria:
      i. The program is at a hospital that has inpatient facilities, operative suites and diagnostic treatment facilities, outpatient facilities, and educational resources.
      ii. The program is at an institution that has a proven commitment to graduate medical education.
      iii. The program director must have current certification in the sub-specialty by the American Board of Orthopedic Surgery, the American Board of Plastic Surgery, or American Board of Surgery.
      iv. The program should have at least 2 physician faculty members with hand surgery experience and current medical licensure who are actively involved in the instruction and supervision of fellows during the time of accredited education.
      v. The program is at a hospital that has affiliated rehabilitation medicine services.
      vi. The program has the resources, including adequate clinical facilities, laboratory research facilities, and appropriately trained faculty and staff, to provide research experience.
   c. At least 2 years of consecutive and independent practice of hand surgery and must have completed a minimum number of upper limb procedures as the primary surgeon according to *Table J-1* below. This includes completion of pre-operative assessments and post-operative care for a minimum of 90 days after surgery. These procedures must be documented in a log that includes the date of the procedure 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. Surgery of the hand includes only those procedures performed on the upper limb below the elbow.

Table J-1: Minimum Procedures for Upper Limb Primary Transplant Surgeons

Type of Procedure	Minimum Number of Procedures
Bone	20
Nerve	20
Tendon	20
Skin or Wound Problems	14

Type of Procedure	Minimum Number of Procedures
Contracture or Joint Stiffness	10
Tumor	10
Microsurgical Procedures Free flaps	10
Non-surgical management	6
Replantation or Transplant	5

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 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 at 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.

2. Completion of at least *one* of the following:
    a. Any ACGME–approved fellowship program in otolaryngology, plastic, oral and maxillofacial, or craniofacial surgery.
    b. A fellowship program in otolaryngology, plastic, oral and maxillofacial, or craniofacial surgery that meets *all* of the following criteria:
        i. The program is at a hospital that has inpatient facilities, operative suites and diagnostic treatment facilities, outpatient facilities, and educational resources.
        ii. The program is at an institution that has a proven commitment to graduate medical education.

iii. The program director must have current certification in the sub-specialty by the American Board of Plastic Surgery, the American Board of Otolaryngology, or the American Board of Oral and Maxillofacial Surgery.

iv. The program should have at least two physician faculty members with head and neck surgery experience and current medical licensure who are actively involved in the instruction and supervision of fellows during the time of accredited education.

v. The program is at a hospital that has affiliated rehabilitation medicine services.

vi. The program has the resources, including adequate clinical facilities, laboratory research facilities, and appropriately trained faculty and staff, to provide research experience.

c. At least 2 years of consecutive and independent practice of head and neck surgery. The surgeon must have completed at least 1 face transplant as primary surgeon or first-assistant, or a minimum number of head and neck procedures as the primary surgeon according to *Table J-2* below. This includes completion of pre-operative assessments and post-operative care for a minimum of 90 days after surgery. These 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, Donor ID, 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.

Table J-2: Minimum Procedures for Head and Neck Primary Transplant Surgeons

Type of Procedure	Minimum Number of Procedures
Facial trauma with bone fixation	10
Head or neck free tissue reconstruction	10

C. Additional Primary Surgeon Requirements for Abdominal Wall Transplant Programs

The primary surgeon for an abdominal wall transplant program must meet the primary transplant surgeon requirements of a head and neck, intestine, kidney, liver, pancreas, or upper limb transplant program.

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 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 body parts it will transplant in the application. 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. 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. Have performed the pre-operative evaluation of at least 3 potential VCA transplant patients.
4. Have current working knowledge in the surgical specialty, defined as independent practice in the specialty over a consecutive five-year period.
5. 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 above have been met by the primary surgeon.

J.3 Primary VCA Transplant Physician Requirements

Each designated VCA transplant program must have a primary transplant physician who meets at least *one* of the following requirements:

- Is currently the primary transplant surgeon or primary transplant physician at a designated transplant program
- Fulfills the requirements of a primary transplant surgeon or primary transplant physician at a designated transplant program according to the OPTN Bylaws
- Is a physician with an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction and who meets *all* of the following additional requirements:
  1. The physician must be accepted onto the hospital's medical staff, and be on-site at this hospital.
  2. The physician must have documentation from the hospital's credentialing committee that it has verified the physician's state license, board certification, training, and transplant continuing medical education, and that the physician is currently a member in good standing of the hospital's medical staff.
  3. The physician must have completed an approved transplant fellowship in a medical or surgical specialty. Approved transplant fellowships for each organ are determined according to the requirements in OPTN Bylaws *Appendices E* through *I*.

4. The physician must have current board certification by the American Board of Medical Specialties or the Royal College of Physicians and Surgeons of Canada.

   In place of current certification by the American Board of Medical Specialties or the Royal College of Physicians and Surgeons of Canada, the physician 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 physician 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 transplant programs not employed by the applying hospital. These letters must address:
      i. Why an exception is reasonable.
      ii. The physician's overall qualifications to act as a primary VCA transplant physician.
      iii. The physician'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 physician 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 physician 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 physician 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.

Appendix M: Definitions

Vascularized Composite Allograft (VCA)

A transplant involving any body parts that meets *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 body parts designated by the OPTN as VCAs, see Vascularized Composite Allograft (VCA) in *OPTN Policy 1.2: Definitions*.

OPTN Policies

1.2 Definitions

Vascularized Composite Allograft (VCA)
A transplant involving any body parts that meet *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.

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