

Membership Requirements for VCA Transplant Programs

Sponsoring Committee:	VCA Committee
Policy/Bylaws Affected:	OPTN Bylaws, Appendix J
Distributed for Public Comment:	January 2015 to March 2015
Amended After Public Comment:	Yes
Effective Date:	Pending programming and notice to members

Problem Statement

Current OPTN Bylaws do not include specific training and experience requirements for key personnel at VCA transplant programs. The VCA Committee proposed minimal certification, training, and experience for individuals serving as primary transplant physicians and surgeons at VCA programs.

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 new Bylaws outline key personnel certification, training, and experience requirements, and include a:

- Certification requirement, or clinical experience pathway in lieu of certification
- Formal training requirement, or clinical experience pathway in lieu of completing formal training

What Members Need to Do

The approved membership requirements for VCA Transplant Programs represent a significant change from the previous membership requirements. Once effective, transplant hospitals with designated VCA programs will need to reapply for OPTN approval. UNOS will give you advance notice of when these Bylaws changes will be effective. This will allow you to submit your program application and for the MPSC to review it before the implementation date.

These changes will be effective once they have been programmed into the system and you have been notified. Once implemented, your hospital will need to ensure that key VCA program personnel meet or exceed the certification, training, and experience requirements outlined below.

Affected Policy/Bylaw Language:

New language is underlined and language that will be deleted is ~~struck through~~.

Appendix J:

Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs

This appendix describes the 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.

J.1 Letter of Notification

If a transplant hospital member commits to performing VCA transplants the hospital must send written notification of this intent to the OPTN Contractor. The notification to the OPTN Contractor must include a written assurance from the local OPO that it will provide organs for use in vascularized composite allografts.

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. A reconstructive surgeon 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. A transplant physician or transplant surgeon 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.

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.

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 current approval for and maintain a designated kidney, liver, heart, lung, or pancreas transplant program

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

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

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 *Appendix D.5.B, Surgeon and Physician Coverage*.

J.2 Primary VCA Transplant Physician Requirements

Each designated VCA transplant program must have a primary transplant physician who is (1) currently designated as the primary transplant surgeon or primary transplant physician at an active solid organ

transplant program, (2) meets the requirements of a primary transplant surgeon or primary transplant physician in the OPTN Bylaws, or (3) who meets *all* of the following requirements:

1. The physician 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 physician must be accepted onto the hospital's medical staff, and be on-site at this hospital.
3. 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.
4. 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.

J.3 Primary VCA Transplant Surgeon Requirements

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

1. The primary 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 primary surgeon must be accepted onto the hospital's medical staff, and be on-site at this hospital.
3. The primary 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 primary surgeon must have observed at least 2 multi-organ procurements.

A. Additional Primary Surgeon Requirements for Upper Limb Transplant Programs

In addition to the requirements as described in J.3 above, the surgeon for an upper limb transplant program must meet the following:

1. Must meet at least *one* of the following:
 - a. Have current certification by the American Board of Plastic Surgery, the American Board of Orthopedic Surgery, the American Board of Surgery, or the foreign equivalent. 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 renewal for an additional 12-month period.
 - b. If the surgeon does not have board certification, the surgeon may qualify by gaining all of the relevant clinical experience as outlined below. As of September 1, 2018, this pathway will no longer be available and all primary surgeons must meet the requirements of paragraph 1A.
 - i. Observation of at least 2 multi-organ procurements and acted as the first-assistant or primary surgeon on at least 1 VCA procurement.
 - ii. Pre-operative evaluation of at least 3 potential upper limb transplant patients.
 - iii. Acted as primary surgeon of a least 1 upper limb transplant.
 - iv. Post-operative follow-up of at least 1 upper limb recipient for 1 year post-transplant.
The multi-organ 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. If a primary surgeon qualified under 1.b ends his involvement with the transplant program, the program must identify a primary transplant surgeon who meets the requirements under 1.a.

2. Completion of at least one of the following:
 - a. Completion of a fellowship program in hand surgery that is approved by the MPSC. Any Accreditation Council of Graduate Medical Education (ACGME) approved fellowship program is automatically accepted by the MPSC.
 - b. Completion of a fellowship program in hand surgery that meets all of the following criteria will also be accepted:
 - i. The program is located at a hospital that has inpatient facilities, operative suites and diagnostic treatment facilities, outpatient facilities, and educational resources.
 - ii. The program is located 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 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. The surgeon must have 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 shown in 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

<u>Type of Procedure</u>	<u>Minimum Number of Procedures</u>
<u>Bone</u>	<u>20</u>
<u>Nerve</u>	<u>20</u>
<u>Tendon</u>	<u>20</u>
<u>Skin or Wound Problems</u>	<u>14</u>
<u>Contracture or Joint Stiffness</u>	<u>10</u>
<u>Tumor</u>	<u>10</u>
<u>Microsurgical Procedures</u>	
<u>Free flaps</u>	<u>10</u>
<u>Non-surgical management</u>	<u>6</u>
<u>Replantation or Transplant</u>	<u>5</u>

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

In addition to the requirements as described in J.3 above, the transplant surgeon for a head and neck transplant program must meet at least *one* of the following:

1. Must meet at least *one* of the following:
 - a. 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 foreign equivalent. 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 renewal for an additional 12-month period.
 - b. If the surgeon does not have board certification, the surgeon may qualify by gaining all of the relevant clinical experience as outlined below. As of September 1, 2018, this pathway will no longer be available and all primary surgeons must meet the requirements of paragraph 1.a.
 - i. Observe at least 2 multi-organ procurements and acted as the first-assistant or primary surgeon on at least 1 VCA procurement.
 - ii. Pre-operative evaluation of at least 3 potential head and neck transplant patients.
 - iii. Primary surgeon of a least 1 head and neck transplant.
 - iv. Post-operative follow up of at least 1 head and neck recipient for 1 year post-transplant.

The multi-organ 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 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. If a primary surgeon qualified under 1.b ends his involvement with the transplant program, the program must identify a primary transplant surgeon who meets the requirements under 1.a.

2. Completion of at least *one* of the following:
 - a. Completion of a fellowship program in otolaryngology, plastic, oral and maxillofacial, or craniofacial surgery that is approved by the MPSC. Any ACGME–approved fellowship program is automatically accepted by the MPSC.
 - b. Completion of 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, 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. The surgeon must have 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 as shown in 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 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. In addition to the requirements as described in J.3 above, the primary surgeon for other VCA transplant programs must meet *all* of the following:

1. Specify the type or types of VCA transplant the surgeon will perform.
2. Have current American Board of Medical Specialties certification or the foreign equivalent in a specialty relevant to the type of VCA transplant the surgeon will be performing.
3. Have gained all of the relevant clinical experience as outlined below:
 - a. Observe at least 2 multi-organ procurements.
 - b. 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. Assembled a multidisciplinary surgical team that includes the primary surgeon with board certification in the relevant surgical specialty and other 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, 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. The team must have demonstrated detailed planning and cadaver rehearsals that are specific to the type or types of VCA transplant the program will perform.

A letter from the presiding institutional executive of the institution where the VCA will be performed must provide written notification that requirements 1-5 above have been met.