

At-a-Glance

Membership Requirements for Vascularized Composite Allograft Transplant Programs

- **Affected/Proposed Policy:** OPTN Bylaws, Appendix J
- **Vascularized Composite Allograft (VCA) Committee**

Vascularized Composite Allografts (VCAs) were included in the OPTN Final Rule (42 CFR part 121) as covered human organs effective July 3, 2014. In response to this change, the OPTN Board of Directors approved minimal VCA membership requirements that will expire on September 1, 2015. Under the current rules, there are no specific membership requirements with regard to VCA transplant experience for the primary physician and surgeon at a VCA program. The VCA Committee is proposing minimal certification, training, and experience for individuals serving as VCA primary physicians and surgeons. If approved, these new requirements will replace those requirements that will expire in September 2015.

- **Number of Potential Candidates Affected**

All U.S. OPOs responded to a survey given by the Association of Organ Procurement Organizations (AOPO) in February 2014 asking to describe actual and planned VCA activity in their Donation Service Area (DSA). The survey found that 28 patients had received VCA transplants at 11 different transplant centers between 1999 and 2014.

Since July 3, 2014, 21 transplant hospitals have received approval for a VCA transplant program. Between July 3, 2014 and December 26, 2014, there have been four VCA transplants in the U.S. As of December 26, 2014, there were nine VCA candidates waiting for a transplant at six transplant hospitals.

- **Compliance with OPTN Strategic Goals and Final Rule**

This proposal meets Goal 4 in the OPTN Strategic Plan:

Promote transplant recipient safety

Establishing more specific membership requirements for VCA transplant programs addresses the key goal outlined above by:

- Promoting accountability to the OPTN
- Establishing objective requirements for the OPTN to assess qualifications of key personnel at VCA transplant programs

- **Specific Requests for Comment**

- Is there a minimum number of VCA transplants that need to be performed before new membership requirements for a future VCA type are created (e.g.: lower limb or larynx)?

Membership Requirements for VCA Programs

Affected Bylaws:

OPTN Bylaws, Appendix J

Vascularized Composite Allograft (VCA) Committee

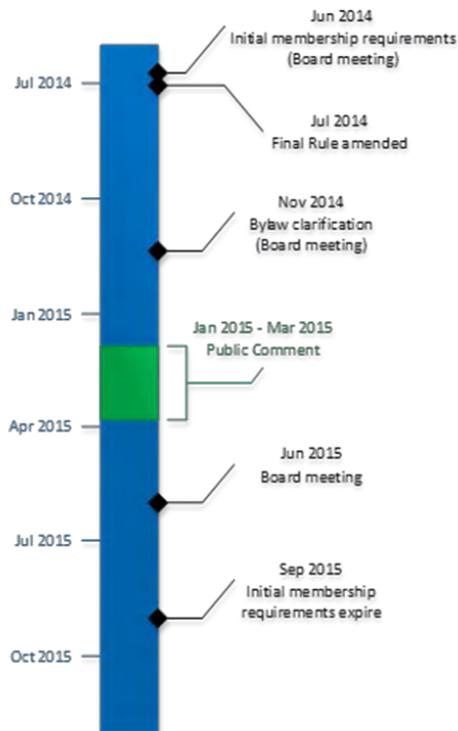
Public comment response period: January 27, 2015 – March 27, 2015

Summary and Goals of the Proposal:

Vascularized Composite Allografts (VCAs) were included in the OPTN Final Rule (42 CFR part 121) as covered human organs effective July 3, 2014. In response to this change, the OPTN Board of Directors approved minimal VCA membership requirements that will expire on September 1, 2015. Under the current rules, there are no specific membership requirements with regard to VCA transplant experience for the primary physician and surgeon at a VCA program. The VCA Committee is proposing minimal certification, training, and experience for individuals serving as VCA primary physicians and surgeons. If approved, these new requirements will replace those requirements that will expire in September 2015.

Background and Significance of the Proposal:

As the OPTN Contractor, UNOS is a membership organization, which is required under the National Organ Transplant Act (NOTA) to establish membership and medical criteria for allocating organs. In order to register and transplant patients, a transplant hospital must meet these requirements and be approved for OPTN membership by the Membership and Professional Standards Committee (MPSC) and the Board of Directors.



In June 2014, the OPTN Board of Directors approved minimal requirements for VCA programs, including:

- Letter of intent from a transplant hospital to perform VCA transplants
- Identification of the reconstructive surgeon and transplant specialist responsible for the VCA program
- Assurance from the local OPO that VCAs will be provided for use in transplantation
- Letter of intent signed by the reconstructive surgeon and transplant physician, and the chief administrative officer of the hospital.

These requirements were intended to be inclusive of VCA transplant programs in operation before the July 3, 2014 additions to the OPTN Final Rule.¹ The OPTN/UNOS Board of Directors approved these membership requirements at their June 2014 meeting.²

The VCA Committee later proposed a clarification to the Board at their November 2014 meeting.³ This clarification would require transplant hospitals to specify the type or types of VCAs they will transplant. Additionally, the assurance from the local OPO would be required to specify the type of types of VCAs that will be recovered from deceased donors. This clarification was approved by the Board and will be effective on February 1, 2015.

The consensus of the Committee was to develop more robust and specific membership requirements. The work of the Subcommittee since July 2014 represents the next phase in the development of more specific membership requirements for VCA programs. Influence on these new membership requirements was drawn from the existing framework in the OPTN Bylaws for organ-specific membership requirements and the American Society of Transplant Surgeon's (ASTS) necessary elements for VCA transplant programs.⁴ The underpinnings of this process were to balance in the desire to be inclusive of pioneering VCA physicians and surgeons, promote patient safety, enable advancement of this emerging area of transplantation, while transitioning VCA transplantation under the structure of the OPTN.

Types of VCA Programs

The Committee's consensus was to focus on membership requirements for the types of VCAs that were most commonly performed. This includes upper limbs, partial and whole faces, and abdominal wall grafts. The proposed bylaw language for partial and whole face was initially drafted under the term "Craniofacial". The use of "Craniofacial" created some confusion among the Subcommittee and other reconstructive surgeons. Use of this term eliminated the possibility that a vascularized scalp transplant would be included under this category. This terminology was seen as problematic as a surgeon who may perform a face transplant is likely well qualified to perform a vascularized scalp transplant. The Subcommittee decided to include face transplant under title "Head and Neck" (Appendix J.3.B). "Head and Neck" will include those grafts above the shoulders, inclusive of facial, vascularized scalp, and larynx grafts.

¹ See 78 FR 40033 available at <https://www.federalregister.gov/articles/2013/07/03/2013-15731/organ-procurementand-transplantation-network>.

² Policy notice is available here: http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Policy_Notice_07-01-2014.pdf.

³ Policy Notice is available here: http://optn.transplant.hrsa.gov/media/1140/policy_notice_12-2014.pdf.

⁴ Cendales, L., Granger, D., Henry, M., Jones, J., Langnas, A., Levi, D., Magee, J., Merion, R., Olthoff, K., Pruett, T., Roberts, J. and Abecassis, M., (2011), "Implementation of Vascularized Composite Allografts in the United States: Recommendations From the ASTS VCA Ad Hoc Committee and the Executive Committee", *American Journal of Transplantation*, 11: 13–17. doi: 10.1111/j.1600-6143.2010.03374.x

The Committee felt it prudent to provide requirements for VCA programs that were yet to be identified (Appendix J.3.D). If the Subcommittee did not establish requirements for new types of VCAs, there would effectively be no membership requirements and transplantation of a new VCA type would be prohibited. This would be detrimental to this emerging area of transplantation.

The Committee felt it would be appropriate for a transplant hospital applying for “other” VCA types (outside of upper limb, head and neck, and abdominal wall) to submit separate applications for each VCA graft the transplant hospital intends to perform. This would be akin to the practice of submitting a separate application for the expansion of transplant services at a hospital to include additional solid organs.

As different types of VCA transplants become more common, the Committee will develop membership requirements and applications specific to those types of transplants.

Key Personnel

The bylaw framework for VCA transplant programs mirrors that of other organ transplant programs: each VCA program would be required to have a program director, a primary transplant physician, and a primary transplant surgeon. Definitions of each of these individuals are included in the OPTN Bylaws, Appendices D and M.⁵ The Committee felt it would be acceptable for one individual to be the program director for multiple VCA programs at different institutions. This practice is currently permitted in the OPTN Bylaws and most often occurs between adult and pediatric solid organ transplant programs at separate institutions in the same city.

The requirements for the primary transplant physician include the option for this position to be filled by a qualified transplant physician or transplant surgeon. This is in recognition of select transplant surgeon’s expertise in transplant medicine and managing a transplant recipient’s immunosuppression needs. The proposed requirements for primary physicians includes requirements for board certification and completion of fellowship training much akin to existing bylaw requirements for other organ transplant programs.

Detailed requirements were also drafted for primary transplant surgeon qualifications. These proposed requirements include board certification and completion of fellowship training much akin to existing bylaw requirements for other solid organ programs. The Committee recognized the possibility that well-qualified VCA surgeons may not meet both the new board certification and fellowship training requirements. Therefore, the Committee has included experience pathways for these legacy VCA surgeons. The Committee agreed these experience pathways could be amended or removed in the future as board certification and fellowship training for VCA transplant surgeons becomes universal.

The Committee added an “expiration date” for the experience pathway in lieu of board certification for primary surgeons. After September 1, 2018, all applicants for primary surgeons must be board certified. Qualifying under an experience pathway can only be used once by an individual VCA program. If a primary surgeon at a VCA program qualified under the experience pathway (in lieu of board certification) leaves a transplant hospital prior to the “expiration date”, the transplant hospital must identify a replacement who is board certified in an appropriate discipline outlined in Appendix J.

⁵ http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Bylaws.pdf#nameddest=Appendix_D
http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Bylaws.pdf#nameddest=Appendix_M

The VCA Committee presented the proposed bylaws language to the MPSC on December 10, 2014. The MPSC suggested the following modifications, and these were added to the proposed language:

- Note in Appendix J that a VCA program must be co-located at a transplant hospital with another approved solid organ transplant program.
- Add kidney and pancreas transplant surgeons to the list of individuals who are qualified to be the primary transplant surgeon for an abdominal wall transplant program.

Additionally, the MPSC inquired if training programs for head and neck include the necessary microvascular experience for the primary surgeon and suggested this experience needed to be more prominently stated. The VCA Committee may identify this experience more specifically in post-public comment changes (e.g.: increasing the number of procedures in trauma and microsurgery from 10 to 20 and inclusion of facial nerve operations/dissections).

The Committee approved the proposed bylaw language regarding Membership Requirements for VCA Transplant Programs during a conference call on December 12, 2014 (Yes – 9, No – 0, Abstentions – 0). Additionally, the VCA Committee unanimously recommended to the OPTN/UNOS Executive Committee that the proposal be distributed for public comment.

Supporting Evidence and/or Modeling:

Influence on the construct of the proposed VCA membership requirements was drawn from existing OPTN membership requirements for other organ transplant programs and the ASTS necessary elements for VCA transplant programs. Requirements for multi-organ observations were sourced from OPTN Bylaws, Appendix E.4.B.3 for primary kidney transplant physicians. However, Committee members from OPOs felt a minimum of two multi-organ procurements was an appropriate number of observations for VCA surgeons.

The Committee recognized the thresholds for experience pathway proposed for head and neck, and “other” VCA transplant programs were derived from clinical consensus instead of from statistical analyses. VCA transplantation is a low-volume procedure with 32 transplants performed in the U.S. historically. This is akin to the manner in which experience pathways for other low-volume organ transplant programs were developed. The exception this is the experience pathway for upper limb surgeons. These case numbers were drawn from the Subspecialty Certificate in Surgery of the Hand from the American Society for Surgery of the Hand (ASSH).⁶ Additions to these cases in the area of microsurgery and replantation/transplantation were added by the Committee.

Expected Impact on Living Donors or Living Donation:

Instances of VCA living donation are rare but have been documented in medical literature. These include transfer of omentum between identical twins for scalp reconstruction⁷, transfer of abdominal wall tissue for breast reconstruction between identical twins⁸, and limb transplant between separated conjoined twins (one twin had known un-survivable condition prior to separation)⁹. However, limiting the proposed VCA membership criteria to only instances of deceased donor VCA transplantation would leave a gap in ensuring patient safety of living donors, should such cases occur in the future.

⁶ <http://www.assh.org/About-ASSH/Get-Involved/Join-ASSH/-Subspecialty-Certificate-in-Surgery-of-the-Hand>

⁷ Buncke, H., Scand, J., (1982), *Plastic and Reconstructive Surgery Supplement*, 19: 81-93

⁸ Allen, R.et al., (2008), *Plastic and Reconstructive Surgery*, 122 (4): 1019-23

⁹ Zuker, R., et al., (2011), *American Journal of Transplantation*, 11 (12): 2762-7

OPTN Policy 14.7.C outlines that organs from living donors can only be recovered from transplant hospitals that are approved to perform living donor recovery for that organ type.¹⁰ The OPTN does not yet have approval criteria for living donor recovery hospitals for VCAs. Therefore, any VCA recovery from a living donor must take place at a transplant hospital that is approved for VCA transplantation involving grafts from deceased donors.

Expected Impact on Specific Patient Populations:

The proposed membership requirements for VCA transplant programs applies to key leadership personnel of the transplant programs and not to all physicians and surgeon involved with the VCA program. As a result of these significant changes to membership requirements, VCA transplant programs approved between July 3, 2014 and the implementation of new membership criteria would be required to reapply for OPTN membership. Transplant hospitals may need additional time for these key personnel to obtain the required experience or recruit personnel with the required experience. This may lead to rare instances of patient access issues for those patients interested in VCA transplantation if a previously approved VCA transplant program experiences an extended gap period in OPTN approval.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

This proposal meets Goal 4 of the OPTN Strategic Plan:

- Promote transplant recipient safety

Establishing more specific membership requirements for VCA transplant programs addresses the key goal outlined above by:

- Promoting accountability to the OPTN
- Establishing objective requirements for the OPTN to assess qualifications of key VCA transplant program personnel

Plan for Evaluating the Proposal:

The submission of applications and the successful designation and approval of VCA transplant programs at member transplant hospitals will be the basis for evaluating this proposal. The VCA Committee will monitor for emerging VCA transplants and assess if new membership requirements may be needed. Additionally, the VCA Committee will monitor the membership requirements to ensure these are consistent with clinical practice and the OPTN Strategic Plan.

Additional Data Collection:

This proposal does not require additional Tiedi® data collection. Membership changes would be collected with new VCA transplant program applications or changes to an approved VCA program's key personnel.

Expected Implementation Plan:

If public comment on this proposal is favorable, this proposal will be submitted to the OPTN Board of Directors in June 2015. If passed, the proposal would require the creation of an application and subsequent review by the U.S. Office of Management and Budget (OMB). Implementation of these new bylaw requirements would follow and be pending programming and notice to OPTN members.

¹⁰ http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Policies.pdf#nameddest=Policy_14

This proposal is a significant change in membership requirements for VCA transplant programs. All OPTN-approved VCA transplant programs would need to reapply for OPTN membership. Key personnel purposed to fill primary transplant physician or primary transplant surgeon roles would need to meet OPTN membership criteria in effect at the time of the program's application. UNOS staff will create a formal application for transplant hospitals to complete and submit. The MPSC will review these VCA applications with collaboration from the VCA Committee and may offer interim approval. Final approval for a VCA program will rest with the OPTN/UNOS Board of Directors.

After September 1, 2018, all applicants for primary physicians or surgeons must be board certified. Qualifying under an experience pathway can only be used once by a VCA program. If a primary surgeon at a VCA program qualified under the experience pathway (in lieu of board certification) leaves a transplant hospital prior to the "expiration date", the transplant hospital must identify a replacement who is board certified in an appropriate discipline outlined in Appendix J.

Communication and Education Plan:

Information about the new requirements will be included in the following routine communication vehicles:

- Policy notice
- System notice
- Presentation at Regional Meetings
- OPTN website

Compliance Monitoring:

The MPSC will review the VCA transplant program applications to determine compliance with these proposed Bylaws. Upon implementation, the OPTN Contractor will facilitate the key personnel change process and the MPSC will review key personnel change applications to ensure ongoing compliance with the Bylaws when changes to a transplant program's primary surgeon or primary physician occur.

Policy or Bylaw Proposal:

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

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 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>10</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, 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 extensive microvascular experience including replantation, revascularization, free tissue transfer, and major flap surgery. 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.