

**OPTN/UNOS Vascularized Composite Allograft (VCA) Transplantation Committee  
Report to the Board of Directors  
December 1-2, 2015  
Atlanta, GA**

**Sue V. McDiarmid, M.D., Chair  
L. Scott Levin, M.D., FACS, Vice Chair**

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*This report reflects the work of the OPTN/UNOS VCA Committee during the May to November 2015 period.*

**Action Items**

None

**Committee Projects**

None

**Committee Projects Pending Implementation**

1. Membership Requirements for VCA Transplant Programs

*Public Comment:* [January 27 – March 27, 2015](#)

*Board Approval:* [June 2015](#)

*Implementation:* Q2/Q3 2016 (estimated)

Just prior to the June 2015 Board meeting, representatives from the Health Resources and Services Administration (HRSA) Division of Transplantation notified UNOS staff and leadership of the Vascularized VCA Committee that the HRSA Office of General Counsel noted an inconsistency between the OPTN Final Rule and OPTN Policy/Bylaw language pertaining to VCAs. Specifically, the OPTN Final Rule directs the OPTN to identify covered body parts in any policies specific to vascularized composite allografts. As written, the OPTN Policies and Bylaws are not sufficiently specific to the covered body parts that are VCAs. The VCA Committee (Committee) has begun work on policy and bylaw language amendments to be consistent with the OPTN Final Rule. If considered by the Board in June 2016, this project will not be implemented in full until sometime in 2017.

The estimated implementation of the Membership Requirements for VCA Transplant Programs (second or third quarter 2016) conflicts with the timeline for the Committee's work on amendments to policy and bylaw language. The OPTN/UNOS Executive Committee will sponsor a proposal to the Board to proceed with implementation of membership requirements for abdominal wall, head and neck, and upper limb VCA transplant programs. Additionally, the Executive Committee will ask the Board to delay the implementation of the detailed requirements for "Other" VCA transplant programs, and in lieu of these detailed requirements, ask the Board to insert the general requirements that are currently in place for all VCA transplant programs.

See the **Executive Committee's Report to the Board** and **Exhibit A** of that report for further details.

**Implemented Committee Projects**

2. VCA Implementation

*Board Approval:* [June 2014](#) (Approved with a sunset)

*Public Comment:* [September 29 – December 5, 2014](#)

*Board Approval:* [June 2015](#) (Approved without a sunset)

*Implementation:* September 1, 2015

## OPTN/UNOS VCA Committee

On June 24, 2014, the OPTN/UNOS Board of Directors approved the VCA Implementation proposal with a sunset date of September 1, 2015. This proposal was approved pending public comment in the fall of 2014. The delay in public comment solicitation was due to the pending change to the OPTN Final Rule that included VCAs under the definition of “covered human organs” on July 3, 2014.

Following public comment in the fall of 2014, the Board approved the VCA Implementation Proposal without a sunset provision June 2, 2015. No programming was required for this project and it was implemented on September 1, 2015.

As of October 23, 2015, there were 51 approved VCA transplant programs located at 23 unique transplant hospitals. Since July 3, 2014, 20 VCA candidates have been registered with the OPTN and nine VCA transplants have occurred. As of October 23, 2015, there are 8 VCA candidates currently waiting for a transplant.

The following data will be periodically provided to the VCA Committee, including, but not limited to:

- The number of VCA candidates and transplants by region, by center, and by basic demographics (e.g., VCA organ type, age, gender, ethnicity, ABO blood group, CPRA)
- Reasons for bypass or refusal of VCA organ offers

### 3. VCA Data Collection and Submission

*Public Comment:* [September 29 – December 5, 2014](#)

*Board Approval:* [June 2015](#)

*Implementation:* [September 1, 2015](#)

This proposal is the first attempt to collect transplant and follow-up data on VCA recipients for the immediate purposes of evaluating outcomes and ensuring patient safety. VCA-specific data elements were identified for collection at two standard intervals used by the OPTN; the time of transplant, and at follow-up (six months post-transplant and annually thereafter). Additionally, this project updated data submission requirements in OPTN Policies 18.1 and 18.2. The project addressed the following topics:

- Specific data elements to be collected on VCA recipients at transplant and follow-up
- Members responsible for submitting VCA organ transplant candidate, recipient, and donor data
- The time period that VCA organ transplant candidate, recipient, and donor data must be submitted to the OPTN

VCA Data Collection was implemented on September 1, 2015 and is performed using an interim solution, pending TIEDI integration. The programming phase of the project is on the IT Roadmap for Q2 2016.

The following data will be provided to the VCA Committee when sufficient amounts of data are available, including, but not limited to:

- Patient socio-demographics and clinical characteristics
- General physical and mental health
- Organ function
- Graft and patient survival
- Immunosuppression
- Acute rejection

## **Review of Public Comment Proposals**

The Committee reviewed two proposals released for public comment from August 14 to October 14, 2015.

### 4. Increase Committee Terms to Three Years (Policy Oversight Committee)

Vascularized Composite Allograft (VCA) Committee discussed this proposal during their in-person meeting. Under the current bylaws, 50% of the committee composition is turning over each year. This

## OPTN/UNOS VCA Committee

translates to a decline in the institutional memory of any committee. Given the level of experience that exists on the VCA Committee and the lack of experienced persons in the community, the impact of member turnover is very real. Further, three year terms for the VCA Committee are critically important, especially in light of the development of the field. The Committee unanimously supports three-year terms for regional and at-large representatives, and leadership of OPTN Committees.

### 5. Reduce Documentation Shipped With Organs (OPO Committee)

The Committee members supported the intent of the proposal; to reduce the administrative burden of record duplication to on-site OPO coordinators, and to allow OPO coordinators more time at the bedside to manage donors. However, the Committee members noted that technological limitations in DonorNet® do not allow VCA transplant program staff to access a donor's electronic records. VCA transplant programs currently rely on faxed and emailed donor records, and verbal reports when considering VCA offers.

Based on the presentation, the Committee felt there needs to be consideration for circumstances present in VCA donation that are not present for other organs. This may be in the form of a policy exemption for VCA donors, and would require an OPO to provide a hard-copy of the complete donor record with a recovered VCA. There is precedent for the use of policy exemptions for VCAs with the earlier VCA Implementation proposal approved by the Board in June 2014, and again in June 2015. This exemption would need to remain in place until the time that VCAs are integrated into DonorNet®.

## Other Committee Work

### 6. Survey to Identify Barriers to VCA Authorization and Recovery

Modifications to the OPTN Final Rule in 2014 included VCAs as covered human organs, thus under the purview of the OPTN. Prior to this time, VCA transplantation largely occurred at a local level and donors were identified by OPOs that had developed protocols and clinical practices with a VCA program. OPOs that did not have existing relationships with a VCA transplant program likely did not consider a potential donor for VCA donation. Further, OPOs without protocols and clinical practices for VCA donation are highly unlikely to pursue authorization for VCA recovery.

The Committee is interested in learning about actual and perceived barriers to VCA authorization and recovery through a survey of OPOs. The results of this survey will help guide future education and data collection projects. A working group consisting of members of the VCA and OPO Committees has drafted a survey with anticipated distribution in January 2016 and analysis in late March/early April 2016.

For more information, see the Committee meeting summary from [September 22, 2015](#).

### 7. List Covered Body Parts in OPTN Bylaws and Policies Pertaining to VCA

The OPTN Final Rule requires the OPTN to implement policies and procedures that identify all covered body parts in any policies specific to vascularized composite allografts defined in §121.2. Analysis from HRSA's Office of General Counsel identified that current OPTN Bylaws and Policies do not specify these covered body parts. OPTN Bylaws and Policies pertaining to Vascularized Composite Allografts (VCAs) are therefore inconsistent with the OPTN Final Rule. The OPTN and VCA Committee need to further specify the specific body parts that fall under the purview of the OPTN.

The Committee has initiated early discussions on the policy impact of this new project. For more information, see the Committee meeting summary from [October 28, 2015](#).

### 8. Uterus Transplantation

The Committee has initiated early discussions on the emerging area of uterus transplantation. To-date, there are no OPTN policies or bylaws that apply specifically to uterus donation and transplantation. With this, there may be the need to provide guidance of this emerging area of transplantation to promote patient safety. The Committee asked UNOS staff to research the feasibility of forming a working group involving interested OPTN committee members and external stakeholders (e.g.: members of the OB/GYN and reproductive medicine communities).

## OPTN/UNOS VCA Committee

For more information, see the Committee meeting summary from [October 28, 2015](#).

### **Meeting Summaries**

The committee held meetings on the following dates:

- June 16, 2015
- July 22, 2015
- September 22, 2015
- October 28, 2015

Meetings summaries for this Committee are available on the OPTN website at:

<http://optn.transplant.hrsa.gov/converge/members/committeesDetail.asp?ID=140>

*OPTN/UNOS Executive Committee*

# Modifications to OPTN Bylaws, Appendix J: Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs

*Committee Liaison  
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UNOS Policy Department*

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# Modifications to OPTN Bylaws, Appendix J: Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs

*Mini-Brief*

## Executive Summary

In June 2015, the OPTN/UNOS Board of Directors (Board) approved amendments to the OPTN Bylaws, Appendix J that established detailed membership requirements for vascularized composite allograft (VCA) transplant programs. These changes outlined membership requirements for upper limb, head and neck, abdominal wall, and “other” VCA transplant program types. Additionally, the Board approved the previous, more general, membership requirements be effective until the detailed membership requirements are implemented. Following the Board meeting, the OPTN/UNOS Executive Committee approved the implementation of the Membership Requirements for VCA Transplant Programs for the second quarter of 2016.

Just prior to the June 2015 Board meeting, representatives from the Health Resources and Services Administration (HRSA) Division of Transplantation notified UNOS staff and leadership of the VCA Committee that the HRSA Office of General Counsel noted an inconsistency between the OPTN Final Rule and OPTN Policy/Bylaw language pertaining to VCAs. Specifically, the OPTN Final Rule directs the OPTN to identify covered body parts in any policies specific to vascularized composite allografts<sup>1</sup>. As written, the OPTN Policies and Bylaws do not consistently specify the covered body parts that are VCAs. The VCA Committee has begun work on policy and bylaw language amendments to be consistent with the OPTN Final Rule.

The anticipated implementation of the Membership Requirements for VCA Transplant Programs (second quarter 2016) conflicts with the timeline for the VCA Committee’s work on amendments to policy and bylaw language. As a result, the Executive Committee is asking the Board to delay the implementation of the detailed membership requirements for “other” VCA program types until policy and bylaw language addressing VCA specificity are resolved.

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<sup>1</sup> §42 CFR 121.4(e)(3) <http://www.ecfr.gov/cgi-bin/text-idx?SID=bb60e0a7222f4086a88c31211cac77d1&mc=true&node=pt42.1.121&rgn=div5>

# Modifications to OPTN Bylaws, Appendix J: Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs

*Affected Policies:* OPTN Bylaws, Appendix J (Membership Requirements for VCA Transplant Programs – J.1, J.1.A-J.1.F, and J.2)

*Sponsoring Committee:* OPTN/UNOS Executive Committee

## What problem will this proposal solve?

In June 2015, the OPTN/UNOS Board of Directors (Board) approved amendments to the OPTN Bylaws, Appendix J that established detailed membership requirements for vascularized composite allograft (VCA) transplant programs. These changes outlined membership requirements for upper limb, head and neck, abdominal wall, and “other” VCA transplant program types. Additionally, the Board approved the previous, more general, membership requirements be effective until the detailed membership requirements are implemented. Following the Board meeting, the OPTN/UNOS Executive Committee approved the implementation of the Membership Requirements for VCA Transplant Programs for the second quarter of 2016.

Just prior to the June 2015 Board meeting, representatives from the Health Resources and Services Administration (HRSA) Division of Transplantation notified UNOS staff and leadership of the VCA Committee that the HRSA Office of General Counsel noted an inconsistency between the OPTN Final Rule and OPTN Policy/Bylaw language pertaining to VCAs. Specifically, the OPTN Final Rule directs the OPTN to identify covered body parts in any policies specific to vascularized composite allografts. As written, the OPTN Policies and Bylaws do not consistently specify the covered body parts that are VCAs. The VCA Committee has begun work on policy and bylaw language amendments to be consistent with the OPTN Final Rule.

The anticipated implementation of the Membership Requirements for VCA Transplant Programs (second quarter 2016) conflicts with the timeline for the VCA Committee’s work on amendments to policy and bylaw language.

## Why should you support this proposal?

Implementing membership requirements is a resource-intensive project for the OPTN. This involves creation of membership applications, review by the U.S. Office of Management and Budget, and expenditure of IT resources for programming. UNOS leadership believes it premature to implement membership requirements for “Other” VCA transplant programs while the VCA Committee develops amendments to Appendix J. Additionally, these amendments are needed to ensure the OPTN Policies and Bylaws are consistent with the OPTN Final Rule. The Committee is therefore asking the Board to not implement Bylaws Appendix J.3.D: Additional Primary Surgeon Requirements for Other VCA Transplant Programs, until policy and bylaw language addressing VCA specificity is resolved. Once language

regarding VCA specificity is resolved, the VCA Committee will bring an updated proposal back to the Board.

In lieu of the language on membership requirements for “Other” VCA transplant programs approved in June 2015, the Committee is asking the Board to retain the existing general VCA membership requirements, outlined in the Policy and Bylaw section of the Mini-brief below. Procedurally, the Committee is asking to revert to the membership requirements previously approved by the Board. This proposal will allow currently approved “Other” VCA transplant programs to maintain their program designation. Additionally, this proposal will allow transplant hospitals that wish to perform VCA transplants other than upper limbs, head and necks, and abdominal walls, a mechanism to apply to OPTN.

## How does this proposal support the OPTN Strategic Plan?

1. *Increase the number of transplants:* There is no impact on this goal.
2. *Improve equity in access to transplants:* There is no impact on this goal.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* This specific proposal has no impact on this goal. However, the previously Board approved VCA membership proposal would establish objective requirements for the OPTN/UNOS to assess qualifications of key VCA transplant program personnel.
4. *Promote living donor and transplant recipient safety:* There is no impact on this goal.
5. *Promote the efficient management of the OPTN:* This proposal makes OPTN Policies and Bylaws consistent with the requirements of the Final Rule.

## How will the OPTN implement this proposal?

This proposal requests a delay in the implementation of Board-approved language and maintains the status quo (general membership requirements) regarding membership requirements for “Other” VCA transplant program types. Similar to the OPO Committee’s proposal to delay the implementation of Imminent and Eligible Death Data Definition, the Committee’s proposal to delay implementation of membership requirements for “Other” VCA transplant programs will not go out for public comment.

Only the Board is empowered to make amendments to the OPTN Bylaws as outlined in the Code of Virginia<sup>2</sup>, and OPTN/UNOS Bylaw Article X<sup>3</sup>. Because this proposal amends language in the OPTN Bylaws, the Committee is required to submit the proposal for Board consideration.

The OPTN will continue to direct new notification letters from transplant hospitals to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review. The OPTN will communicate the changes to Bylaws, Appendix J through a policy notice to the transplant community.

Although this proposal will not directly require programming in UNet<sup>SM</sup>, the proposal will be effective pending programming of the membership requirements approved by the Board in June 2015 and notice to OPTN members. This will avoid the circumstance of membership requirements being effective before programming is completed. There will be instructional support required for this proposal.

## How will members implement this proposal?

The currently approved “other” VCA transplant programs will not be impacted by this proposal. If this proposal is approved, transplant hospitals that wish to apply for a VCA program type, other than

<sup>2</sup> VA Code § 13.1-869 (2013) <http://law.lis.virginia.gov/vacode/title13.1/chapter10/section13.1-869/>

<sup>3</sup> OPTN Bylaws, Article X

[http://optn.transplant.hrsa.gov/ContentDocuments/OPTN\\_Bylaws.pdf#nameddest=Article\\_10](http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Bylaws.pdf#nameddest=Article_10)

abdominal wall, head and neck, and upper limb, will follow requirements already in existence. This process requires a letter of notification from the transplant hospital with the following:

1. The specific 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 who qualifies by documented transplant experience in a medical or surgical specialty.

**Will this proposal require members to submit additional data?**

No, this proposal does not require additional data collection.

**How will members be evaluated for compliance with this proposal?**

The MPSC will still plan to review VCA transplant program applications and key personnel change applications for head and neck, upper limb, and abdominal wall to determine compliance with the proposed Bylaws once implemented. For other VCA programs, the MPSC process for review will not change from the process as it exists today; the MPSC will review notification letters for new applicants and changes to identified individuals.

**Policy or Bylaw Language**

**RESOLVED, that changes to OPTN Bylaws Appendix J (Membership Requirements for VCA Transplant Program), as set forth in Exhibit A of the Executive Committee’s report to the Board, are hereby approved, effective pending programming and notice to OPTN members.**

- 1 **Appendix J:**
- 2 **Membership Requirements for Vascularized**
- 3 **Composite Allograft (VCA) Transplant Programs**
- 4 ~~This appendix describes the information and documentation transplant hospitals must provide when:~~
- 5 ~~This appendix describes the documentation transplant hospitals must provide when requesting approval~~
- 6 ~~as a designated VCA transplant program.~~
- 7 ~~■ Submitting a completed membership application to apply for approval for each designated VCA~~
- 8 ~~transplant program.~~
- 9 ~~■ Completing a Personnel Change Application for a change in key personnel at each designated VCA~~
- 10 ~~transplant program.~~

## **J.1 Membership Requirements for Abdominal Wall, Head and Neck, and Upper Limb VCA Transplant Programs**

Appendix J.1 applies only to abdominal wall, head and neck, and upper limb VCA transplant programs.

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.A 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.6.B, Surgeon and Physician Coverage*.

### **J.21.B 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.31.C Primary VCA Transplant Surgeon Requirements**

Each designated VCA transplant program must have a primary transplant surgeon that meets *all*

59 of the following requirements:

60

61 1. The primary surgeon must have an M.D., D.O., or equivalent degree from another country,  
62 with a current license to practice medicine in the hospital's state or jurisdiction.

63 2. The primary surgeon must be accepted onto the hospital's medical staff, and be on-site at  
64 this hospital.

65 3. The primary surgeon must have documentation from the hospital's credentialing committee  
66 that it has verified the surgeon's state license, training, and continuing medical education,  
67 and that the surgeon is currently a member in good standing of the hospital's medical staff.

68 4. The primary surgeon must have observed at least 2 multi-organ procurements.

69

### 70 **J.3.A1.D Additional Primary Surgeon Requirements for Upper Limb** 71 **Transplant Programs**

72 In addition to the requirements as described in J.1.C above, the surgeon for an upper limb  
73 transplant program must meet the following:

74

75

1. Must meet at least *one* of the following:

76

a. Have current certification by the American Board of Plastic Surgery, the American Board  
77 of Orthopedic Surgery, the American Board of Surgery, or the foreign equivalent. In the  
78 case of a surgeon who has just completed training and whose board certification is  
79 pending, the Membership and Professional Standards Committee (MPSC) may grant  
80 conditional approval for 24 months to allow time for the surgeon to complete board  
81 certification, with the possibility of renewal for an additional 12-month period.

82

b. If the surgeon does not have board certification, the surgeon may qualify by gaining all of  
83 the relevant clinical experience as outlined below. As of September 1, 2018, this pathway  
84 will no longer be available and all primary surgeons must meet the requirements of  
85 paragraph 1A.

86

i. Observation of at least 2 multi-organ procurements and acted as the first-assistant or  
87 primary surgeon on at least 1 VCA procurement.

88

ii. Pre-operative evaluation of at least 3 potential upper limb transplant patients.

89

iii. Acted as primary surgeon of a least 1 upper limb transplant.

90

iv. Post-operative follow-up of at least 1 upper limb recipient for 1 year post-transplant.

91

92

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

99

100 If a primary surgeon qualified under 1.b ends his involvement with the transplant program, the  
101 program must identify a primary transplant surgeon who meets the requirements under 1.a.

102

103

2. Completion of at least *one* of the following:

104

a. Completion of a fellowship program in hand surgery that is approved by the MPSC. Any  
105 Accreditation Council of Graduate Medical Education (ACGME) approved fellowship  
106 program is automatically accepted by the MPSC.

107

- 108 b. Completion of a fellowship program in hand surgery that meets *all* of the following criteria  
 109 will also be accepted:  
 110  
 111 i. The program is located at a hospital that has inpatient facilities, operative suites  
 112 and diagnostic treatment facilities, outpatient facilities, and educational resources.  
 113 ii. The program is located at an institution that has a proven commitment to graduate  
 114 medical education.  
 115 iii. The program director must have current certification in the sub-specialty by the  
 116 American Board of Orthopedic Surgery, the American Board of Plastic Surgery, or  
 117 American Board of Surgery.  
 118 iv. The program should have at least 2 physician faculty members with hand surgery  
 119 experience and current medical licensure who are actively involved in the  
 120 instruction and supervision of fellows during the time of accredited education.  
 121 v. The program at a hospital that has affiliated rehabilitation medicine services.  
 122 vi. The program has the resources, including adequate clinical facilities, laboratory  
 123 research facilities, and appropriately trained faculty and staff, to provide research  
 124 experience.  
 125  
 126 c. The surgeon must have at least 2 years of consecutive and independent practice of hand  
 127 surgery and must have completed a minimum number of upper limb procedures as the  
 128 primary surgeon shown in *Table J-1* below. This includes completion of pre-operative  
 129 assessments and post-operative care for a minimum of 90 days after surgery. These  
 130 procedures must be documented in a log that includes the date of the procedure and the  
 131 medical record number or other unique identifier that can be verified by the OPTN  
 132 Contractor. This log must be signed by the program director, division chief, or department  
 133 chair where the experience was gained. Surgery of the hand includes only those  
 134 procedures performed on the upper limb below the elbow.  
 135  
 136

**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
Contracture or Joint Stiffness	10
Tumor	10
Microsurgical Procedures	10
Free flaps	10
Non-surgical management	6
Replantation or Transplant	5

137  
 138 **J.3.B1.E Additional Primary Surgeon Requirements for Head and Neck**  
 139 **Transplant Programs**

140 In addition to the requirements as described in J.1.C above, the transplant surgeon for a  
 141 head and neck transplant program must meet at least *one* of the following:  
 142

- 143 1. Must meet at least *one* of the following:  
 144 a. Have current certification by the American Board of Plastic Surgery, the  
 145 American Board of Otolaryngology, American Board of Oral and Maxillofacial  
 146 Surgery, the American Board of Surgery, or the foreign equivalent. In the case of

147 a surgeon who has just completed training and whose board certification is  
 148 pending, the Membership and Professional Standards Committee (MPSC) may  
 149 grant conditional approval for 24 months to allow time for the surgeon to  
 150 complete board certification, with the possibility of renewal for an additional 12-  
 151 month period.

152  
 153 b. If the surgeon does not have board certification, the surgeon may qualify by  
 154 gaining all of the relevant clinical experience as outlined below. As of September  
 155 1, 2018, this pathway will no longer be available and all primary surgeons must  
 156 meet the requirements of paragraph 1.a.

- 157  
 158 i. Observe at least 2 multi-organ procurements and acted as the first-  
 159 assistant or primary surgeon on at least 1 VCA procurement.  
 160 ii. Pre-operative evaluation of at least 3 potential head and neck transplant  
 161 patients.  
 162 iii. Primary surgeon of a least 1 head and neck transplant.  
 163 iv. Post-operative follow up of at least 1 head and neck recipient for 1 year  
 164 post-transplant.

165 The multi-organ procurement experience must be documented in a log that  
 166 includes the Donor ID or other unique identifier that can be verified by the OPTN  
 167 Contractor. The experience for head and neck procedures must be documented  
 168 in a log that includes the dates of procedures and evaluations, the role of the  
 169 surgeon, and the medical record number or other unique identifier that can be  
 170 verified by the OPTN Contractor. This log must be signed by the program  
 171 director, division chief, or department chair where the experience was gained.

172  
 173 If a primary surgeon qualified under 1.b ends his involvement with the transplant  
 174 program, the program must identify a primary transplant surgeon who meets the  
 175 requirements under 1.a.

- 176  
 177 2. Completion of at least *one* of the following:  
 178 a. Completion of a fellowship program in otolaryngology, plastic, oral and  
 179 maxillofacial, or craniofacial surgery that is approved by the MPSC. Any  
 180 ACGME–approved fellowship program is automatically accepted by the MPSC.  
 181 b. Completion of a fellowship program in otolaryngology, plastic, oral and  
 182 maxillofacial, or craniofacial surgery that meets all of the following criteria:  
 183  
 184 i. The program is at a hospital that has inpatient facilities, operative suites  
 185 and diagnostic treatment facilities, outpatient facilities, and educational  
 186 resources.  
 187 ii. The program is at an institution that has a proven commitment to  
 188 graduate medical education.  
 189 iii. The program director must have current certification in the sub-specialty  
 190 by the American Board of Plastic Surgery, the American Board of  
 191 Otolaryngology, American Board of Oral and Maxillofacial Surgery.  
 192 iv. The program should have at least two physician faculty members with  
 193 head and neck surgery experience and current medical licensure who  
 194 are actively involved in the instruction and supervision of fellows during  
 195 the time of accredited education.  
 196 v. The program is at a hospital that has affiliated rehabilitation medicine  
 197 services.

- 198 vi. The program has the resources, including adequate clinical facilities,
- 199 laboratory research facilities, and appropriately trained faculty and staff,
- 200 to provide research experience.
- 201
- 202 c. The surgeon must have at least 2 years of consecutive and independent practice
- 203 of head and neck surgery. The surgeon must have completed at least 1 face
- 204 transplant as primary surgeon or first-assistant, or a minimum number of head
- 205 and neck procedures as the primary surgeon as shown in *Table J-2* below. This
- 206 includes completion of pre-operative assessments and post-operative care for a
- 207 minimum of 90 days after surgery. These procedures must be documented in a
- 208 log that includes the dates of procedures and evaluations, the role of the surgeon
- 209 and the medical record number, Donor ID, or other unique identifier that can be
- 210 verified by the OPTN Contractor. This log must be signed by the program
- 211 director, division chief, or department chair where the experience was gained.
- 212
- 213

**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

214

215 **J.3.C1.F Additional Primary Surgeon Requirements for Abdominal Wall**

216 **Transplant Programs**

217 The primary surgeon for an abdominal wall transplant program must meet the primary transplant

218 surgeon requirements of a head and neck, intestine, kidney, liver, pancreas, or upper limb

219 transplant program.

220 **~~D. Additional Primary Surgeon Requirements for Other VCA Transplant~~**

221 **~~Programs~~**

222 ~~This pathway is only for the primary transplant surgeon at a VCA program intending to transplant~~

223 ~~body parts other than those that will be transplanted at approved upper limb, head and neck, or~~

224 ~~abdominal wall transplant programs. In addition to the requirements as described in J.3 above,~~

225 ~~the primary surgeon for other VCA transplant programs must meet all of the following:~~

- 226 ~~1. Specify the type or types of VCA transplant the surgeon will perform.~~
- 227
- 228 ~~2. Have current American Board of Medical Specialties certification or the foreign equivalent in a~~
- 229 ~~specialty relevant to the type of VCA transplant the surgeon will be performing.~~
- 230 ~~3. Have gained all of the relevant clinical experience as outlined below:~~
- 231 ~~b. Observe at least 2 multi-organ procurements.~~
- 232 ~~c. Pre-operative evaluation of at least 3 potential VCA transplant patients.~~
- 233
- 234 ~~4. Have current working knowledge in the surgical specialty, defined as independent practice in~~
- 235 ~~the specialty over a consecutive five-year period.~~
- 236 ~~5. Assembled a multidisciplinary surgical team that includes the primary surgeon with board~~
- 237 ~~certification in the relevant surgical specialty and other specialists necessary to complete the~~
- 238 ~~VCA transplant including, for example, plastic surgery, orthopedics, otolaryngology, obstetrics~~
- 239 ~~and gynecology, urology, or general surgery. This team must include a team member that~~
- 240 ~~has microvascular experience such as replantation, revascularization, free tissue transfer,~~
- 241

242 and major flap surgery. These procedures must be documented in a log that includes the  
243 dates of procedures, the role of the surgeon, and the medical record number, Donor ID, or  
244 other unique identifier that can be verified by the OPTN Contractor. This log must be signed  
245 by the program director, division chief, or department chair where the experience was gained.  
246 The team must have demonstrated detailed planning and cadaver rehearsals that are specific  
247 to the type or types of VCA transplant the program will perform.

248  
249 A letter from the presiding institutional executive of the institution where the VCA will be  
250 performed must provide written notification that requirements 1-5 above have been met.  
251

252 **J.2 Letter of Notification for VCA transplant programs, other than abdominal**  
253 **wall, head and neck, and upper limb**

254  
255 If a transplant hospital member commits to performing VCA transplants, other than abdominal wall, head  
256 and neck, and upper limb, the hospital must send a written notification to the OPTN Contractor that  
257 includes both of the following:

- 258
- 259 1. The specific types of VCA transplant the hospital will perform.
- 260 2. If the member will perform deceased donor VCA transplants, assurance from the local OPO that it will  
261 provide the same type or types of VCA for transplantation.
- 262

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

- 264
- 265 1. The chief administrative officer for the institution.
- 266 2. The reconstructive surgeon for each type of VCA transplant with expertise in microsurgical  
267 reconstruction, prior experience in VCA, or in lieu of actual VCA experience, extensive experience in  
268 the applicable reconstructive procedure as required, such as hand replantation or facial  
269 reconstruction.
- 270 3. The transplant physician or transplant surgeon for each type of VCA transplant at an approved  
271 transplant program that has completed an approved transplant fellowship, or who qualifies by  
272 documented transplant experience in a medical or surgical specialty.
- 273

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

276 #