

List Covered Body Parts Pertaining to VCA

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Executive Summary

The Organ Procurement and Transplantation Network (OPTN) is required by the OPTN Final Rule to implement policies related to vascularized composite allografts (VCAs) and identify all covered body parts in any policies specific to VCAs. Current OPTN/UNOS Bylaws and Policies do not consistently specify these covered body parts. This proposal contains a list of covered body parts to include in OPTN/UNOS Bylaws and Policies in order to meet the requirements of the Final Rule.

The list of covered body parts is not an endorsement of research on a new type of organ transplant by the U.S. Department of Health and Human Services or the OPTN. Instead, the intent of these modifications is to make the OPTN/UNOS Bylaws and Policies consistent with the federal regulation, to provide transparency in what body parts are considered VCAs, and to define the scope of oversight by the OPTN.

List Covered Body Parts Pertaining to VCA

Affected Policies and Bylaws: OPTN/UNOS Bylaws Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs, Appendix J: Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs, Appendix M: Definitions; and OPTN/UNOS Policy 1.2: Definitions.

Sponsoring Committee: VCA Committee

Public Comment Period: January 25, 2016 to March 25, 2016

What problem will this proposal solve?

The Final Rule requires the OPTN to implement policies related to VCAs and to identify all covered body parts in any policies specific to VCAs.¹ In July 2013, the Secretary of the Department of Health and Human Services (HHS) responded to comments received from the notice of potential rulemaking. Specifically, the Secretary noted that the OPTN would be required to list all covered body parts for transparency.² Current OPTN Bylaws and Policies do not consistently specify these covered body parts. Without specifying what body parts are VCAs, it is unclear what body parts are organs that fall under the auspices of the OPTN, compared to what body parts are included in the definition of human cells, tissues,

¹ **Vascularized Composite Allograft (VCA)**

A transplant involving any body parts that meets all nine of the following criteria:

1. That is vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation.
2. Containing multiple tissue types.
3. Recovered from a human donor as an anatomical/structural unit.
4. Transplanted into a human recipient as an anatomical/structural unit.
5. Minimally manipulated (i.e., processing that does not alter the original relevant characteristics of the organ relating to the organ's utility for reconstruction, repair, or replacement).
6. For homologous use (the replacement or supplementation of a recipient's organ with an organ that performs the same basic function or functions in the recipient as in the donor);
7. Not combined with another article such as a device.
8. Susceptible to ischemia and, therefore, only stored temporarily and not cryopreserved.
9. Susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.

² 42 CFR 121, OPTN Final Rule, accessed May 5, 2016, <https://www.federalregister.gov/articles/2013/07/03/2013-15731/organ-procurement-and-transplantation-network>

and cellular and tissue-based products (HCT/Ps) governed by the U.S. Food and Drug Administration (FDA).³

This proposal does not address the source of VCAs, whether from deceased or living donors. For guidance on VCAs from living donors, see the Guidance Document on VCAs from Living Donors on the OPTN website.⁴ For guidance on deceased VCA donor authorization, see Guidance for Organ Procurement Organizations (OPOs) for VCA Deceased Donor Authorization on the OPTN website.⁵

Why should you support this proposal?

The proposal modifies OPTN Bylaws and Policies to be consistent with federal regulation, to provide transparency in what body parts are VCA transplants, and define the scope of VCA oversight by the OPTN.

How was this proposal developed?

In July 2015, the Health Resources and Services Administration (HRSA) notified UNOS and the VCA Committee (Committee) of an inconsistency between the OPTN Final Rule and the OPTN Bylaws and Policies pertaining to VCAs. The current OPTN Bylaws and Policies do not consistently specify what covered body parts are VCAs. HRSA subsequently requested the OPTN and the Committee to specify the covered body parts that fall under the purview of the OPTN.

The OPTN Final Rule provides the legal definition of VCA using nine criteria.⁶ The Committee considered the implications of a VCA meeting the nine criteria but not appearing on the list. HRSA explained that legally, a body part is a VCA, and thus an organ, if it meets the entire list of nine criteria in the Final Rule even if the OPTN Bylaws and Policies do not include it on the list of VCAs covered by the Bylaws and Policies. Because body parts that meet the list of nine criteria are organs, they are governed by the National Organ Transplant Act (NOTA) and the Final Rule. The absence of specific OPTN Bylaws and Policies only affects whether the OPTN provides oversight over the specific VCA organ type.

The Committee was concerned about the process and timeline required to modify the list of covered body parts in OPTN Bylaws and Policies. Proposed changes to OPTN Bylaws and Policies usually require a minimum of six to nine months for the Committee to diligently develop a proposal, distribute the proposed change for public comment, and to earn Board approval. The Committee was concerned that this extended period could permit an emerging VCA transplant to occur without the knowledge of the OPTN, with no mechanism to collect data on the donation and outcome of the transplant. The Committee was also concerned about the potential impact of a bad outcome on the entire field of VCA transplantation.

The Committee, composed of members with subject matter expertise in the fields of transplant medicine and transplant and reconstructive surgery, developed the list based on clinical consensus. The

³ 21 CFR 1270, Human Tissues Intended for Transplantation, accessed May 5, 2016, <https://www.gpo.gov/fdsys/pkg/CFR-2012-title21-vol8/xml/CFR-2012-title21-vol8-part1270.xml>

⁴ Organ Procurement and Transplantation Network, accessed May 5, 2016, <https://optn.transplant.hrsa.gov/resources/by-organ/vascular-composite-allograft/vcas-from-living-donors/>

⁵ Organ Procurement and Transplantation Network, accessed May 5, 2016, https://optn.transplant.hrsa.gov/media/1137/vca_donor_guidance.pdf

⁶ 42 CFR 121, accessed May 5, 2016, <http://www.ecfr.gov/cgi-bin/text-idx?SID=bb60e0a7222f4086a88c31211cac77d1&mc=true&node=pt42.1.121&rgn=div5>

Committee considered what body parts should appear on the list in light of the types of VCAs already included in membership applications submitted to the OPTN, types of VCA transplants that have been performed, and types of potential emerging VCA transplants. At the outset, the Committee decided to create a holistic list inclusive of all body parts that meet the legal definition of a VCA, regardless of whether anybody was currently considering their use as a VCA. The nomenclature used is intended to be broad enough to capture vascularized allografts that are anatomically linked and those that may fall under the umbrella of a surgical specialty, as HRSA clarified that the intent of the regulatory language was not to require granular detail for each specific body part. Therefore, using nomenclature of, and similar to, “Upper Limb” is acceptable.

In December 2015, the Committee discussed the types of VCAs as well as specific examples that would fall under each type. The Committee unanimously approved the following:

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

How well does this proposal address the problem statement?

The primary goal of this proposal is for OPTN Bylaws and Policies to be consistent with the Final Rule. The list of covered body parts is not an endorsement of research on a new type of organ transplant by the Department of Health and Human Services or the OPTN. The intent of these modifications is for the OPTN Bylaws and Policies to be compliant to federal regulation, to provide transparency in what body parts are VCA organs, and to define the scope of oversight by the OPTN. In that regard, the proposal addresses the problem statement well.

Current VCA Transplantation in the U.S.

Beginning in July 2014, transplant hospitals began to submit applications to the OPTN to perform VCA transplants (**Table 1**).

Table 1. Approved VCA Transplant Programs as of April 15, 2016.

VCA Program Type	N
Upper Limb	18
Head and Neck	17
Abdominal Wall	14
Genitourinary	8
- Uterine	3
- Penile	2

VCA Program Type	N
- Genitourinary, not specified	3
Lower Limb	2
All	59

As of April 15, 2016, there were 59 VCA programs located at 26 transplant hospitals. There were 18 approved upper limb, 17 head and neck, and 14 abdominal wall transplant programs. Upper limb, head and neck, and abdominal wall transplant programs represent the current clinical practice in the U.S. As of April 15, 2016, there has been only one uterus transplant performed and no lower limb VCA transplants have been performed in the U.S. The applications for VCA program types received by the OPTN were considered when creating the list of covered body parts. As a result, the VCA program types in the table above were included in the list of covered body parts.

Emerging VCA Transplants

There are two emerging areas of VCA transplantation where transplant hospitals in the U.S. have verbalized their intent to begin transplants: genitourinary organs, including uterus; and lower limb. Additionally, there are three areas of VCA transplantation where innovation may occur. Those body parts are glands (for example, adrenal and thymus), musculoskeletal composite grafts, and spleen.

Genitourinary Organs

Genitourinary organ transplantation represents one emerging area of VCA transplantation. Both male and female genitalia would be included under this title. These structures could be transplanted in instances of severe trauma or prior surgical complications where urological reconstruction was previously unsuccessful, or not possible.

Since July 3, 2014, eight transplant hospitals have applied for genitourinary/penile/urogenital transplant programs, but no transplants of these organs have occurred since then. The OPTN is not aware of any genitourinary, penile, or urogenital transplants occurring in the U.S. prior to July 3, 2014. However, genitourinary organ transplantation is documented in the media and peer-reviewed literature. The first case of successful male genitalia transplant occurred in South Africa in December 2014.⁷ This transplant was performed on a male recipient who had surgical complications from circumcision. One earlier unsuccessful case occurred in China in 2006.⁸ One recent article profiling a genitourinary transplant program in the U.S. reported more than 1,350 wounded service members have suffered genitourinary

⁷ Bateman, Chris. 2015. "World's First Successful Penis Transplant at Tygerberg Hospital." *South African Medical Journal* 251-252, http://www.scielo.org.za/scielo.php?pid=S0256-95742015000300009&script=sci_arttext&tlng=pt

⁸ Zhang, Li-Chao. 2013. "Ethical Issues in Penile Transplantation." *Asian Journal of Andrology* 795-800, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3739079/pdf/aja201088a.pdf>

trauma in combat between 2001 to 2013.⁹ In addition, individuals with injuries from occupational accidents may benefit from genitourinary transplantation.

Uterus transplantation, which included under the umbrella of genitourinary organs, is an emerging area of VCA transplantation. The OPTN has approved uterus transplant programs at three OPTN-member transplant hospitals as of April 15, 2016. One uterus transplant has occurred since VCAs became governed by the OPTN on July 3, 2014. The OPTN is not aware of any uterus transplants occurring in the U.S. prior to July 3, 2014.

This type of transplant could treat a narrow classification of fertility problems: uterine factor infertility (UFI). Estimates on the incidence of UFI in women of childbearing age have been reported between 3-5%.¹⁰ Uterus transplants may also be an option when surrogacy or adoption is not possible due to ethical, religious, and other reasons. Uterus transplants have been performed internationally in Sweden (with three live births reported¹¹), and in Saudi Arabia and Turkey.¹²

Lower Limb Transplantation

Lower limb transplantation is a second emerging area of VCA transplantation. Lower limb transplantation may be a therapeutic alternative in cases of limb loss due to trauma or pre-existing congenital disorders. There are two approved lower limb transplant programs in the U.S.; however, no lower limb transplants have been performed since VCAs became governed by the OPTN on July 3, 2014. The OPTN is not aware of any lower limb transplants occurring in the U.S. prior to July 3, 2014. One case of lower limb transplant was reported in Spain in July 2011.¹³

Musculoskeletal Composite Graft Transplantation

Musculoskeletal composite graft segments are an area of VCA transplantation where innovation is anticipated. Musculoskeletal grafts may include vascularized allografts for post-traumatic reconstruction or reconstruction for osteomyelitis. Vascularized joint transfers of the ankle, elbow, hip, knee, shoulder or wrist joint may be appropriate in young patients that are not candidates for conventional arthroplasty, or in cases of joint loss due to ballistic injury or infection. Other musculoskeletal composite graft components include functional muscle transfers for functional reconstruction, or coverage of major soft tissue defects.

⁹ Grady, Denise. 2015. "Penis Transplants Being Planned to Help Wounded Troops." *New York Times*, December 6: A1. http://www.nytimes.com/2015/12/07/health/penis-transplants-being-planned-to-heal-troops-hidden-wounds.html?_r=0

¹⁰ Tzakis, Andreas G. 2015. "The First Live Birth Subsequent to Uterus Transplantation." *Transplantation* 8-9, http://journals.lww.com/transplantjournal/Citation/2015/01150/The_First_Live_Birth_Subsequent_to_Uterus.5.aspx.

¹¹ Brannstrom, Mats. 2015. "The Swedish Uterus Transplantation Project: The Story Behind the Swedish Uterus Transplantation Project." *ACTA Obstetrica et Gynecologica* 675-679, <http://onlinelibrary.wiley.com/doi/10.1111/aogs.12661/full>.

¹² Arora, Kavita. 2013. "Uterus Transplantation: Ethical and Regulatory Challenges." *Journal of Medical Ethics*, 396-400.

¹³ Cavadas, P.C. 2013. "Bilateral Transfemoral Lower Extremity Transplantation." *American Journal of Transplantation* 1343-1349.

As of April 15, 2016, there are no approved VCA programs in the U.S. for musculoskeletal composite graft segments.

Gland and Spleen Transplantation

The Committee agreed that glands (for example, adrenal and thymus glands) and spleen transplants represent areas of innovation in VCA transplantation that may occur in the near future. While clinically accepted as “organs”, glands, and spleens are not legally identified as specific human organs in NOTA or the Final Rule. The Committee discussed and agreed that these body parts meet the definition of VCA in the Final Rule according to the nine criteria. Including glands and spleen transplants on a list of covered body parts would legally define them as VCAs and provide transparency that the OPTN has oversight over these organs. As of April 15, 2016, the OPTN has not received any applications for VCA programs seeking to transplant glands or spleens involving living or deceased donors.

Was this proposal changed in response to public comment?

The proposal was distributed for public comment from January 25, 2016 to March 25, 2016. The proposal was included on the non-discussion agenda at the 11 OPTN/UNOS Regional meetings, where it received no comments, and six additional comments were submitted by the public. Of the six comments submitted by professional societies or individuals, only one opposed the proposal. The joint correspondence from the National Catholic Bioethics Center and National Catholic Partnership on Disability objected to the Committee’s proposal. The two Catholic bioethics groups noted their opposition to living VCA donation (with exception of the possibility, in some cases of abdominal wall transplantation), and stated their opposition to the inclusion of reproductive and genitourinary organs in the list of covered body parts. Both groups were concerned the proposal would allow the creation of an irreversible mutilation of healthy function to the living donor, and that certain provisions of the proposal advance potential hazards to the recipients and their future offspring.

The Committee carefully considered these comments during an in-person meeting on April 22, 2016. The Committee understands the role of the OPTN is to facilitate healthcare policy related to organ transplantation as allowed by law. It is outside the purview of the OPTN to prohibit a transplant procedure that is allowed by federal regulation. The responsibility of the OPTN/UNOS would be to evaluate applications and determine if the transplant program met the minimum requirements. However, if the risk to a donor is greater than the benefit to the recipient, a procedure will not be allowed by the OPTN/UNOS. Where allowed by law, it is the responsibility of the OPTN to permit its members and medical teams at those institutions to consider whether to offer emerging therapies to patients.

The Committee considered several changes to OPTN Bylaws and Policies during the April meeting.

Modifications to List of Covered Body Parts

A literature review identified emerging research on thymus transplantation in the setting of heart transplantation.¹⁴ Based on this literature, the Committee added a body part of “glands” to the list to include, for example, adrenal and thymus glands.

The Committee also modified the example in the list of covered body parts that appeared under abdominal wall, specifically “vascularized pelvic elements”. For clarity, the committee modified this example to “vascularized skeletal elements of the pelvis”.

Consistency Across Requirements for the Primary Transplant Surgeon for Upper Limb, and Head and Neck Transplant Programs

The Committee also addressed an inconsistency between the requirements for the primary transplant surgeon of an Upper Limb transplant program (Appendix J.3.A) and a Head and Neck transplant program (Appendix J.3.B). The intent of the Committee’s proposal approved by the Board in June 2015 was that requirements for a primary transplant surgeon of an Upper Limb or Head and Neck transplant program would require both board certification (or experience) and fellowship training (or experience). The bylaw language approved by the Board for the primary surgeon of a head and neck transplant program required at least one board certification (or experience) or fellowship training (or experience). This correction is captured in the bylaw language approved by the Committee.

OPTN Bylaw and Policy Language Modifications

The Committee discussed nonsubstantive modifications for style consistency and clarity. These amendments appear throughout the proposed OPTN Bylaw and Policy language (included at the close of this document). Example of this includes, general requirements for transplant hospitals applying for a VCA transplant program, multidisciplinary transplant exposure for the primary transplant surgeon for other VCA transplant programs, and the removal of the sunset provision of the experience pathway (in lieu of board certification) for the primary transplant surgeon of an Upper Limb, or Head and Neck transplant programs.

The Committee unanimously approved the language as amended and recommended consideration to the OPTN/UNOS Board of Directors.

Which populations are impacted by this proposal?

The primary impact of this proposal will be on transplant hospitals with approved VCA programs. Between July 3, 2015 and April 15, 2016, ten VCA transplants were performed in the U.S. Twelve candidates were waiting for VCA transplants as of April 15, 2016 (**Table 2**).

¹⁴ Schultz, B.D., Mohan, R., Dorafshar, A.H., and Gottlieb, L.J. 2014. “Chest Wall, Thymus, and Heart Vascularized Composite Allograft Proof of Concept Cadaveric Model for Heart Transplantation”, *Annals of Plastic Surgery*, 102-104.

Table 2. VCA Transplants Performed During 7/3/2014 – 4/15/2016 and Candidates Waiting for VCA Transplants as of 4/15/2016 by Type

VCA Type	VCA Transplants, 7/3/2014-4/15/2016	VCA Candidates on the Waiting List as of 4/15/2016
Abdominal Wall	1 (10%)	1 (8%)
Head and Neck: Craniofacial	3 (30%)	2 (17%)
Head and Neck: Scalp	1 (10%)	-
Upper Limb, Bilateral	2 (20%)	5 (42%)
Upper Limb, Unilateral	2 (20%)	3 (25%)
Uterus	1 (10%)	1 (8%)
All	10 (100%)	12 (100%)

Of the ten VCA transplants, one was an abdominal wall transplant, four were head and neck transplants (including three face and one scalp), two were bilateral upper limb transplants, two were unilateral upper limb transplants, and one was a uterus transplant. As of April 15, 2016, one candidate was waiting for an abdominal transplant, five candidates were waiting for bilateral upper limb transplants, three candidates were waiting for unilateral upper limb transplants, two candidates were waiting for face transplants, and one candidate was waiting for a uterus transplant. As of April 15, 2015, there have been no lower limb, genitourinary, penile, or urogenital candidates or transplants performed in the U.S.

This proposal will also impact any hospital seeking to transplant a body part on the list in OPTN Bylaws and Policies. Hospitals must be OPTN members and apply for approval of a VCA transplant program prior to transplanting organs included on the list of covered body parts.

How does this proposal support the OPTN Strategic Plan?

1. *Increase the number of transplants:* There is no impact to this goal
2. *Improve equity in access to transplants:* There is no impact to this goal
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* There is no impact to this goal
4. *Promote living donor and transplant recipient safety:* There is no impact to this goal
5. *Promote the efficient management of the OPTN:* This project will address an inconsistency between the OPTN Final Rule and OPTN Policies and Bylaws pertaining to VCAs.

How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

The submission of applications and the successful designation and approval of VCA programs at member transplant hospitals will be the basis for evaluating this proposal. The following information will be monitored every three months following implementation of the policy for the duration that is to be determined.

- The number of approved VCA programs by type
- The number of candidates added to the VCA waiting list by center and VCA type
- The number of VCA transplants by center and VCA type
- The number of candidates still waiting for VCA by center and VCA type

How will the OPTN implement this proposal?

UNOS staff will amend the formal membership application and the UNOS systems that categorize VCA candidates and transplants to reflect the new list of covered body parts. This will include re-categorizing existing data and modifying the system software so that members can use the new categories when submitting new data. This will impact the process that creates the following worksheets: Transplant Program Contact Information for Organ Offers, VCA Candidate Registration, VCA Candidate List, Candidate Removal, Transplant Recipient Registration, and Transplant Recipient Follow-up.

The revised membership application form has been submitted and must be approved by the U.S. Office of Management and Budget (OMB). The OMB form submission includes changes related to this proposal and related to the membership requirements for VCA transplant programs that were approved at the June 2015 board meeting.

Once the form is approved by the OMB and system changes are complete, the application will be made available to programs and a period of time will be provided for members to submit their new application prior to the two proposals becoming effective.

The MPSC will review these VCA applications in collaboration with the VCA Committee and may offer interim approval. Final approval for a VCA program will rest with the OPTN/UNOS Board of Directors.

How will members implement this proposal?

This proposal will be implemented concurrently with the changes to the membership requirements for VCA transplant programs approved by the Board in June of 2015. As a result of the changes already approved, VCA transplant programs would need to reapply for OPTN/UNOS membership. At the time of that application, the transplant program would have to identify their program type based on the list of covered body parts contained in this proposal.

Will this proposal require members to submit additional data?

New VCA transplant programs must submit an application to the OPTN to be approved for VCA transplantation. The application will be updated to reflect the new list of covered body parts. New information collection will be limited to providing a specific list of options for which body part the applicant wishes to transplant, as stated in this proposal. Consistent with the OPTN Principles of Data Collection, additional data collection will be limited to only that which is necessary to “determine if institutional members are complying with policy.”

How will members be evaluated for compliance with this proposal?

The MPSC will review 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 Language

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

1 **RESOLVED**, that the changes to OPTN Bylaws, Appendices D (Membership Requirements for
2 Transplant Hospital and and Transplant Programs), J (Membership Requirements for Vascularized
3 Composite Allograft Transplant Programs), J.3 (Primary VCA Transplant Surgeon Requirements),
4 M (Definitions), and OPTN Policy 1.2 (Definitions), as set forth below, are hereby approved,
5 pending implementation and notice to OPTN members.
6

7 ***Appendix D:***
8 ***Membership Requirements for Transplant Hospitals and Transplant***
9 ***Programs***

10
11 A transplant hospital member is any hospital that performs organ transplants and has current approval as
12 a designated transplant program for at least one organ.
13

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

- 16 ~~■ *D.5: Transplant Program Director*~~
- 17 ~~■ *D.6: Transplant Program Key Personnel*~~
- 18 ~~■ *D.7: Changes in Key Transplant Program Personnel*~~

19
20 **D.2 Designated Transplant Program Requirement**

21 In order to receive organs for transplantation, a transplant hospital member must have current approval
22 as a designated transplant program for at least one organ. Designated transplant programs must meet at
23 least *one* of the following requirements:
24

- 25 ■ Have approval as a transplant program by the Secretary of the U.S. Department of Health and
26 Human Services (HSS) for reimbursement under Medicare.
- 27 ■ Have approval as a transplant program in a Department of Veterans Affairs, Department of Defense,
28 or other Federal hospital.
- 29 ■ Qualify as a designated transplant program according to the membership requirements of these
30 Bylaws.

31
32 The OPTN does not grant designated transplant program approval for any type of vascularized organ
33 transplantation for which the OPTN has not established specific criteria. In order to perform vascularized
34 organ transplantation procedures for which there are no OPTN-established criteria, including multi-
35 visceral transplants, a hospital must be a transplant hospital member and have current approval as a
36 designated transplant program for at least one of the organ types involved in multi-visceral transplant. In
37 the case of abdominal multi-visceral organ transplants, the transplant hospital must have approval as a
38 designated liver transplant program. ~~In the case of vascularized composite allografts (including, but not~~
39 ~~limited to, faces and upper extremities), the transplant hospital must have approval for at least one~~
40 ~~designated transplant program in addition to the vascularized composite allograft program designation.~~

41 **Appendix J:**
42 **Membership Requirements for Vascularized Composite Allograft**
43 **(VCA) Transplant Programs**

44
45 This appendix describes the information and documentation transplant hospitals must provide when:
46

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

51
52 For approval as a designated VCA transplant program, transplant hospitals must also:
53

- 54 1. Meet general membership requirements, which are described in *Appendix D: Membership*
55 *Requirements for Transplant Hospitals and Transplant Programs*.
- 56 2. ~~Have current approval for and maintain a designated kidney, liver, heart, lung, or pancreas transplant~~
57 ~~program~~ Have approval for at least one designated transplant program in addition to the vascularized
58 composite allograft program designation.

59
60 For more information on the application and review process, see *Appendix A: Membership Application*
61 *and Review*.
62

63 **J.3 Primary VCA Transplant Surgeon Requirements**

64 Each designated VCA transplant program must have a primary transplant surgeon that meets *all* of the
65 following requirements:
66

- 67 1. The primary surgeon must have an M.D., D.O., or equivalent degree from another country, with a
68 current license to practice medicine in the hospital's state or jurisdiction.
- 69 2. The primary surgeon must be accepted onto the hospital's medical staff, and be on-site at this
70 hospital.
- 71 3. The primary surgeon must have documentation from the hospital's credentialing committee that it has
72 verified the surgeon's state license, training, and continuing medical education, and that the surgeon
73 is currently a member in good standing of the hospital's medical staff.
- 74 4. The primary surgeon must have observed at least 2 multi-organ procurements.
75

76 **A. Additional Primary Surgeon Requirements for Upper Limb**
77 **Transplant Programs**

78 In addition to the requirements as described in section J.3 above, the surgeon for an upper limb
79 transplant program must meet both of the following:
80

- 81 1. Must meet at least *one* of the following:
 - 82 a. Have current certification by the American Board of Plastic Surgery, the American Board
83 of Orthopedic Surgery, the American Board of Surgery, or the foreign equivalent. In the
84 case of a surgeon who has just completed training and whose board certification is
85 pending, the Membership and Professional Standards Committee (MPSC) may grant
86 conditional approval for 24 months to allow time for the surgeon to complete board
87 certification, with the possibility of renewal for an additional 12-month period.

- 88 b. If the surgeon does not have board certification, the surgeon may qualify by gaining *all* of
89 the following relevant clinical experience; ~~as outlined below. As of September 1, 2018,~~
90 ~~this pathway will no longer be available and all primary surgeons must meet the~~
91 ~~requirements of paragraph 1a.~~
- 92 i. Observation of at least 2 multi-organ procurements and acted as the first-assistant or
93 primary surgeon on at least 1 VCA procurement.
 - 94 ii. Pre-operative evaluation of at least 3 potential upper limb transplant
95 ~~patients~~candidates.
 - 96 iii. Acted as primary surgeon of a least 1 upper limb transplant.
 - 97 iv. Post-operative follow-up of at least 1 upper limb recipient for 1 year post-transplant.

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

106
107 If a primary surgeon qualified under 1.b ~~ends his involvement with~~leaves the transplant
108 program, the replacement for this surgeon program must identify a primary transplant
109 surgeon who meets the requirements under of 1.a. As of September 1, 2018, pathway
110 1.b will no longer be available and all primary surgeons must meet the requirements of
111 1.a.

- 112
113 2. Completion of at least *one* of the following:
- 114 a. ~~Completion of a~~A fellowship program in hand surgery that is approved by the MPSC. Any
115 Accreditation Council of Graduate Medical Education (ACGME) approved fellowship
116 program is automatically accepted by the MPSC.
 - 117 b. ~~Completion of a~~A fellowship program in hand surgery that meets *all* of the following
118 criteria will also be accepted:
 - 119 i. The program is ~~located~~ at a hospital that has inpatient facilities, operative suites
120 and diagnostic treatment facilities, outpatient facilities, and educational resources.
 - 121 ii. The program is ~~located~~ at an institution that has a proven commitment to graduate
122 medical education.
 - 123 iii. The program director must have current certification in the sub-specialty by the
124 American Board of Orthopedic Surgery, the American Board of Plastic Surgery, or
125 American Board of Surgery.
 - 126 iv. The program should have at least 2 physician faculty members with hand surgery
127 experience and current medical licensure who are actively involved in the
128 instruction and supervision of fellows during the time of accredited education.
 - 129 v. The program is at a hospital that has affiliated rehabilitation medicine services.
 - 130 vi. The program has the resources, including adequate clinical facilities, laboratory
131 research facilities, and appropriately trained faculty and staff, to provide research
132 experience.
 - 133 c. ~~The surgeon must have a~~At least 2 years of consecutive and independent practice of
134 hand surgery and must have completed a minimum number of upper limb procedures as
135 the primary surgeon according to *Table J-1* below. This includes completion of pre-
136 operative assessments and post-operative care for a minimum of 90 days after surgery.

137 These procedures must be documented in a log that includes the date of the procedure
 138 and the medical record number or other unique identifier that can be verified by the
 139 OPTN Contractor. This log must be signed by the program director, division chief, or
 140 department chair where the experience was gained. Surgery of the hand includes only
 141 those procedures performed on the upper limb below the elbow.
 142
 143

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 Free flaps	10
Non-surgical management	6
Replantation or Transplant	5

144
 145 **B. Additional Primary Surgeon Requirements for Head and Neck**
 146 **Transplant Programs**

147 In addition to the requirements as described in section J.3 above, the transplant surgeon for a
 148 head and neck transplant program must meet ~~at least one of~~ both of the following:
 149

- 150 1. Must meet at least *one* of the following:
- 151 a. Have current certification by the American Board of Plastic Surgery, the American Board
 152 of Otolaryngology, American Board of Oral and Maxillofacial Surgery, the American
 153 Board of Surgery, or the foreign equivalent. In the case of a surgeon who has just
 154 completed training and whose board certification is pending, the Membership and
 155 Professional Standards Committee (MPSC) may grant conditional approval for 24 months
 156 to allow time for the surgeon to complete board certification, with the possibility of
 157 renewal for an additional 12-month period.
 - 158 b. If the surgeon does not have board certification, the surgeon may qualify by gaining *all* of
 159 the following relevant clinical experience: ~~as outlined below. As of September 1, 2018,~~
 160 ~~this pathway will no longer be available and all primary surgeons must meet the~~
 161 ~~requirements of paragraph 1.a.~~
 - 162 i. Observation of at least 2 multi-organ procurements and acted as the first-
 163 assistant or primary surgeon on at least 1 VCA procurement.
 - 164 ii. Pre-operative evaluation of at least 3 potential head and neck transplant
 165 patients candidates.
 - 166 iii. Acted as pPrimary surgeon of a least 1 head and neck transplant.
 - 167 iv. Post-operative follow up of at least 1 head and neck recipient for 1 year post-
 168 transplant.

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

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

177
178 If a primary surgeon qualified under 1.b ~~ends his involvement with~~leaves the transplant
179 program, the replacement for this surgeon program must identify a primary transplant
180 surgeon who meets the requirements under of 1.a. As of September 1, 2018, pathway
181 1.b will no longer be available and all primary surgeons must meet the requirements of
182 1.a.

- 183
184 2. Completion of at least *one* of the following:
- 185 a. ~~Completion of a~~A fellowship program in otolaryngology, plastic, oral and maxillofacial, or
186 craniofacial surgery that is approved by the MPSC. Any ACGME–approved fellowship
187 program is automatically accepted by the MPSC.
 - 188 b. ~~Completion of a~~A fellowship program in otolaryngology, plastic, oral and maxillofacial, or
189 craniofacial surgery that meets all of the following criteria:
 - 190 i. The program is at a hospital that has inpatient facilities, operative suites and
191 diagnostic treatment facilities, outpatient facilities, and educational resources.
 - 192 ii. The program is at an institution that has a proven commitment to graduate medical
193 education.
 - 194 iii. The program director must have current certification in the sub-specialty by the
195 American Board of Plastic Surgery, the American Board of Otolaryngology,
196 American Board of Oral and Maxillofacial Surgery.
 - 197 iv. The program should have at least two physician faculty members with head and
198 neck surgery experience and current medical licensure who are actively involved in
199 the instruction and supervision of fellows during the time of accredited education.
 - 200 v. The program is at a hospital that has affiliated rehabilitation medicine services.
 - 201 vi. The program has the resources, including adequate clinical facilities, laboratory
202 research facilities, and appropriately trained faculty and staff, to provide research
203 experience.
 - 204 c. ~~The surgeon must have a~~At least 2 years of consecutive and independent practice of
205 head and neck surgery. The surgeon must have completed at least 1 face transplant as
206 primary surgeon or first-assistant, or a minimum number of head and neck procedures as
207 the primary surgeon according to *Table J-2* below. This includes completion of pre-
208 operative assessments and post-operative care for a minimum of 90 days after surgery.
209 These procedures must be documented in a log that includes the dates of procedures
210 and evaluations, the role of the surgeon and the medical record number, Donor ID, or
211 other unique identifier that can be verified by the OPTN Contractor. This log must be
212 signed by the program director, division chief, or department chair where the experience
213 was gained.

214
215 **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

216
217 **D. Additional Primary Surgeon Requirements for Other VCA Transplant**
218 **Programs**

219 This pathway is only for the primary transplant surgeon at a VCA transplant program intending to
220 transplant body parts other than those that will be transplanted at approved upper limb, head and
221 neck, or abdominal wall transplant programs. The VCA transplant program must specify the body
222 parts it will transplant in the application. In addition to the requirements as described in section
223 J.3 above, the primary surgeon for other VCA transplant programs must meet *all* of the following:
224

- 225 ~~1. Specify the type or types of VCA transplant the surgeon will perform.~~
- 226 1. 2. Have current American Board of Medical Specialties certification or the foreign equivalent in
- 227 a specialty relevant to the type of covered body part the VCA transplant the surgeon will be
- 228 performing transplanting.
- 229 2. 3. Have gained all of the following relevant clinical experience ~~as outlined below:~~
- 230 a. Observation of at least 2 multi-organ procurements.
- 231 b. Pre-operative Participation in the multidisciplinary evaluations of at least 3 potential VCA
- 232 transplant patients candidates.
- 233 3. 4. Have at least 5 years of consecutive and independent practice of current working
- 234 knowledge in the surgical specialty, defined as independent practice in the specialty over a
- 235 consecutive five-year period.
- 236 4. 5. Have assembled a multidisciplinary surgical team that includes the primary surgeon with
- 237 board certification in the relevant surgical specialty and other specialties ~~sists~~ necessary to
- 238 complete the VCA transplant including, for example, such as plastic surgery, orthopedics,
- 239 otolaryngology, obstetrics and gynecology, urology, or general surgery. This team must also
- 240 include a team member that has microvascular experience such as replantation,
- 241 revascularization, free tissue transfer, and or major flap surgery. These procedures must be
- 242 documented in a log that includes the dates of procedures, the role of the surgeon, and the
- 243 medical record number, Donor ID, or other unique identifier that can be verified by the OPTN
- 244 Contractor. This log must be signed by the program director, division chief, or department
- 245 chair where the experience was gained. The team must have demonstrated detailed planning
- 246 and cadaver rehearsals that are specific to the type or types of covered body part the VCA
- 247 transplant the program will perform.

248

249 A letter from the presiding ~~institutional~~ executive of the ~~institution~~ transplant hospital where the

250 VCA transplant will be performed must provide written notification that requirements 1-~~54~~ above

251 have been met.

252

253 **Appendix M: Definitions**

254 **Vascularized Composite Allograft (VCA)**

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

256

- 257 1. That is vascularized and requires blood flow by surgical connection of blood vessels to function after
 - 258 transplantation.
 - 259 2. Containing multiple tissue types.
 - 260 3. Recovered from a human donor as an anatomical/structural unit.
 - 261 4. Transplanted into a human recipient as an anatomical/structural unit.
 - 262 5. Minimally manipulated (i.e., processing that does not alter the original relevant characteristics of the
 - 263 organ relating to the organ's utility for reconstruction, repair, or replacement).
 - 264 6. For homologous use (the replacement or supplementation of a recipient's organ with an organ that
 - 265 performs the same basic function or functions in the recipient as in the donor).
 - 266 7. Not combined with another article such as a device.
 - 267 8. Susceptible to ischemia and, therefore, only stored temporarily and not cryopreserved.
 - 268 9. Susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious
 - 269 disease risk to the recipient.
- 270

271 For the list of covered body parts designated by the OPTN as VCAs, see Vascularized Composite

272 Allografts (VCA) in OPTN Policy 1.2: Definitions.

273

274 **OPTN Policies**

275 **1.2 Definitions**

276 **Vascularized Composite Allograft (VCA)**

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

- 278
- 279 1. That is vascularized and requires blood flow by surgical connection of blood vessels to function after
 - 280 transplantation.
 - 281 2. Containing multiple tissue types.
 - 282 3. Recovered from a human donor as an anatomical/structural unit.
 - 283 4. Transplanted into a human recipient as an anatomical/structural unit.
 - 284 5. Minimally manipulated (i.e., processing that does not alter the original relevant characteristics of the
 - 285 organ relating to the organ's utility for reconstruction, repair, or replacement).
 - 286 6. For homologous use (the replacement or supplementation of a recipient's organ with an organ that
 - 287 performs the same basic function or functions in the recipient as in the donor).
 - 288 7. Not combined with another article such as a device.
 - 289 8. Susceptible to ischemia and, therefore, only stored temporarily and not cryopreserved.
 - 290 9. Susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious
 - 291 disease risk to the recipient.

292

293 The following body parts are considered VCAs:

- 294
- 295 • Upper limb (including, but not limited to, any group of body parts from the upper limb or radial forearm
 - 296 flap)
 - 297 • Head and neck (including, but not limited to, face including underlying skeleton and muscle, larynx,
 - 298 parathyroid gland, scalp, trachea, or thyroid)
 - 299 • Abdominal wall (including, but not limited to, symphysis pubis or other vascularized skeletal elements
 - 300 of the pelvis)
 - 301 • Genitourinary organs (including, but not limited to, uterus, internal/external male and female genitalia,
 - 302 or urinary bladder)
 - 303 • Glands (including, but not limited to adrenal or thymus)
 - 304 • Lower limb (including, but not limited to, pelvic structures that are attached to the lower limb and
 - 305 transplanted intact, gluteal region, vascularized bone transfers from the lower extremity, anterior
 - 306 lateral thigh flaps, or toe transfers)
 - 307 • Musculoskeletal composite graft segment (including, but not limited to, latissimus dorsi, spine axis, or
 - 308 any other vascularized muscle, bone, nerve, or skin flap)
 - 309 • Spleen

310

311 **FURTHER RESOLVED, that the changes to OPTN Bylaws J.3.A (Additional Primary Surgeon**

312 **Requirements for Upper Limb Transplant Programs) and J.3.B (Additional Primary Surgeon**

313 **Requirements for Head and Neck Transplant Programs) are hereby approved, effective September**

314 **1, 2018.**

315

316 **A. Additional Primary Surgeon Requirements for Upper Limb**

317 **Transplant Programs**

318 In addition to the requirements as described in section J.3 above, the surgeon for an upper limb

319 transplant program must meet *both* of the following:

- 320
- 321 1. ~~Must meet at least one of the following:~~
 - 322 a. Have current certification by the American Board of Plastic Surgery, the American Board
 - 323 of Orthopedic Surgery, the American Board of Surgery, or the foreign equivalent. In the

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

328 ~~b. If the surgeon does not have board certification, the surgeon may qualify by gaining all of~~
329 ~~the following relevant clinical experience:~~

- 330 ~~i. Observation of at least 2 multi-organ procurements and acted as the first assistant~~
331 ~~or primary surgeon on at least 1 VCA procurement.~~
- 332 ~~ii. Pre-operative evaluation of at least 3 potential upper limb transplant candidates.~~
- 333 ~~iii. Acted as primary surgeon of at least 1 upper limb transplant.~~
- 334 ~~iv. Post-operative follow-up of at least 1 upper limb recipient for 1 year post-transplant.~~

335
336 ~~The multi-organ procurement experience must be documented in a log that includes the~~
337 ~~Donor ID or other unique identifier that can be verified by the OPTN Contractor. The~~
338 ~~experience for upper limb transplant procedures must be documented in a log that~~
339 ~~includes the dates of procedures and evaluations, the role of the surgeon, and the~~
340 ~~medical record number or other unique identifier that can be verified by the OPTN~~
341 ~~Contractor. This log must be signed by the program director, division chief, or~~
342 ~~department chair where the experience was gained.~~

343
344 ~~If a primary surgeon qualified under 1.b leaves the transplant program, the replacement~~
345 ~~for this surgeon must meet the requirements of 1.a. As of September 1, 2018, pathway~~
346 ~~1.b will no longer be available and all primary surgeons must meet the requirements of~~
347 ~~1.a.~~

348
349 2. Completion of at least *one* of the following:

- 350 a. A fellowship program in hand surgery that is approved by the MPSC. Any Accreditation
351 Council of Graduate Medical Education (ACGME) approved fellowship program is
352 automatically accepted by the MPSC.
- 353 b. A fellowship program in hand surgery that meets *all* of the following criteria will also be
354 accepted:
 - 355 i. The program is at a hospital that has inpatient facilities, operative suites and
356 diagnostic treatment facilities, outpatient facilities, and educational resources.
 - 357 ii. The program is located at an institution that has a proven commitment to graduate
358 medical education.
 - 359 iii. The program director must have current certification in the sub-specialty by the
360 American Board of Orthopedic Surgery, the American Board of Plastic Surgery, or
361 American Board of Surgery.
 - 362 iv. The program should have at least 2 physician faculty members with hand surgery
363 experience and current medical licensure who are actively involved in the
364 instruction and supervision of fellows during the time of accredited education.
 - 365 v. The program is at a hospital that has affiliated rehabilitation medicine services.
 - 366 vi. The program has the resources, including adequate clinical facilities, laboratory
367 research facilities, and appropriately trained faculty and staff, to provide research
368 experience.
- 369 c. At least 2 years of consecutive and independent practice of hand surgery and must have
370 completed a minimum number of upper limb procedures as the primary surgeon
371 according to *Table J-1* below. This includes completion of pre-operative assessments
372 and post-operative care for a minimum of 90 days after surgery. These procedures must

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be documented in a log that includes the date of the procedure and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained. Surgery of the hand includes only those procedures performed on the upper limb below the elbow.

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

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

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

In addition to the requirements as described in section J.3 above, the transplant surgeon for a head and neck transplant program must meet *both* 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 following relevant clinical experience:~~
 - 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 head and neck transplant candidates.~~
 - iii. ~~Acted as 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.

412 ~~If a primary surgeon qualified under 1.b leaves the transplant program, the replacement~~
 413 ~~for this surgeon must meet the requirements of 1.a. As of September 1, 2018, pathway~~
 414 ~~1.b will no longer be available and all primary surgeons must meet the requirements of~~
 415 ~~1.a.~~

- 416 2. Completion of at least *one* of the following:
- 417 a. A fellowship program in otolaryngology, plastic, oral and maxillofacial, or craniofacial
 - 418 surgery that is approved by the MPSC. Any ACGME–approved fellowship program is
 - 419 automatically accepted by the MPSC.
 - 420 b. A fellowship program in otolaryngology, plastic, oral and maxillofacial, or craniofacial
 - 421 surgery that meets all of the following criteria:
 - 422 i. The program is at a hospital that has inpatient facilities, operative suites and
 - 423 diagnostic treatment facilities, outpatient facilities, and educational resources.
 - 424 ii. The program is at an institution that has a proven commitment to graduate medical
 - 425 education.
 - 426 iii. The program director must have current certification in the sub-specialty by the
 - 427 American Board of Plastic Surgery, the American Board of Otolaryngology,
 - 428 American Board of Oral and Maxillofacial Surgery.
 - 429 iv. The program should have at least two physician faculty members with head and
 - 430 neck surgery experience and current medical licensure who are actively involved in
 - 431 the instruction and supervision of fellows during the time of accredited education.
 - 432 v. The program is at a hospital that has affiliated rehabilitation medicine services.
 - 433 vi. The program has the resources, including adequate clinical facilities, laboratory
 - 434 research facilities, and appropriately trained faculty and staff, to provide research
 - 435 experience. - 436 c. At least 2 years of consecutive and independent practice of head and neck surgery. The
 - 437 surgeon must have completed at least 1 face transplant as primary surgeon or first-
 - 438 assistant, or a minimum number of head and neck procedures as the primary surgeon
 - 439 according to *Table J-2* below. This includes completion of pre-operative assessments
 - 440 and post-operative care for a minimum of 90 days after surgery. These procedures must
 - 441 be documented in a log that includes the dates of procedures and evaluations, the role of
 - 442 the surgeon and the medical record number, Donor ID, or other unique identifier that can
 - 443 be verified by the OPTN Contractor. This log must be signed by the program director,
 - 444 division chief, or department chair where the experience was gained.

445 **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

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448

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