

## *Guidance Document for Public Comment*

# Update Guidance on Optimizing VCA Recovery

*OPTN Vascularized Composite Allograft Transplantation Committee*

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# Update Guidance on Optimizing VCA Recovery

*Affected Guidance:* *Guidance on Optimizing VCA Recovery from Deceased Donors*  
*Sponsoring Committee:* *Vascularized Composite Allograft Transplantation Committee*  
*Public Comment Period:* *July 27, 2023- September 19, 2023*

## Executive Summary

This proposed guidance document intends to replace the existing OPTN *Guidance on Optimizing VCA Recovery from Deceased Donors*, which was approved by the OPTN Board of Directors in 2018.<sup>1</sup> This proposed guidance, titled *OPTN Guidance on Optimizing VCA Recovery*, provides guidance pertinent to the current state of the Vascular Composite Allograft (VCA) transplantation field. The OPTN Vascular Composite Allograft Transplantation Committee (the Committee) presents this updated guidance to inform Organ Procurement Organizations (OPOs) and transplant programs on collaborative, effective VCA graft recovery practices. The updated guidance includes a brief history of VCA transplantation and recommendations on identifying and evaluating a potential VCA donor, family considerations, recovery and post-recovery practices, and media and public relations strategies. The updated guidance also omits language from the previous version of this guidance that references the “VCA Candidate List” because when VCA allocation is implemented into the OPTN Computer System, there will be no need for an external process for VCA deceased donor registration and VCA candidate list assessment.

The Committee invites OPOs and transplant programs to provide feedback on additional effective practices for VCA graft recovery and to point out any barriers to becoming more involved in the field of VCA transplantation. This proposed guidance document also seeks the experiences of donor families to further inform discussions regarding the VCA authorization process and effective public relations strategies for media involvement.

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<sup>1</sup> OPTN, *Guidance on Optimizing VCA Recovery from Deceased Donors*, [https://optn.transplant.hrsa.gov/media/2503/vca\\_guidance\\_201806.pdf](https://optn.transplant.hrsa.gov/media/2503/vca_guidance_201806.pdf) (accessed May 19, 2023)

## Background

In 2018, the OPTN Board of Directors approved *Guidance on Optimizing VCA Recovery from Deceased Donors*.<sup>2</sup> This historic guidance contained broad effective practices that applied to general VCA donation as well as specific guidance pertaining to head and neck, and upper limb donation. The guidance provided recommendations on eight topics, including a section with instructions for *Registering a Deceased VCA Donor and Accessing the VCA Candidate List*.

The new, *2023 Guidance on Optimizing VCA Recovery*, which omits "deceased donor" in the title as seen in the 2018 version, provides recommendations relevant to the current state of the VCA field, including living uterus donation. To provide the community with a useful resource, the Committee restructured discussion topics in this updated guidance document. Additionally, the Committee has expanded the updated guidance document's audience from solely OPOs to OPOs, transplant programs already involved with VCA recovery and transplant, and transplant programs considering becoming involved with VCA recovery and transplant. The expansion of the target audience aims to capture the attention of a greater portion of the transplant community and highlight the importance of collaboration between OPOs and transplant programs when engaging in the VCA recovery process.

## Purpose

The purpose of this updated guidance document is to increase the recovery and transplantation of VCA organs. The updated guidance aims to inform the community of VCA graft recovery recommendations and expand VCA visibility in the transplant community. It also intends to provide guidance to OPOs that are currently collaborating, or considering collaboration with VCA transplant programs, and to support VCA programs as they pursue VCA transplantation.

## Recommendations

The 2023 recommendations in the proposed guidance document below are organized into six topics, some of which were updated from the 2018 *Guidance on Optimizing VCA Recovery from Deceased Donors* guidance and some of which are new topics to this 2023 version. The first section, *VCA Background*, introduces the field of VCA with a brief narrative timeline of clinical milestones since the first VCA transplantations in 1998.<sup>3</sup> This section also informs on OPTN purview over VCA organs and the quality of life enhancing benefits of VCA transplantation. The following topic, *Considerations for the Identification and Initial Evaluation of the Potential VCA Donor*, provides recommendations to broaden VCA donor evaluation practices and suggests VCA type specific donor evaluation criteria. The third section, *Family Considerations* gives guidance on strategies and proper preparation when seeking VCA authorization from potential donor families. *Recovery Considerations* covers recommendations for timing and sequence of VCA graft recovery and *Post-Recovery Considerations* informs on practices to be completed after the VCA recovery, such as: communicating with funeral homes and medical examiners, or the use of prosthetics. The last section, *Media and Public Relations Strategies* discusses the need for a communications plan that is aligned with the needs of the donor, recipient, and their families.

<sup>2</sup> OPTN, *Guidance on Optimizing VCA Recovery from Deceased Donors*, [https://optn.transplant.hrsa.gov/media/2503/vca\\_guidance\\_201806.pdf](https://optn.transplant.hrsa.gov/media/2503/vca_guidance_201806.pdf) (accessed May 19, 2023).

<sup>3</sup> Strome M, Stein J, Esclamado R, Hicks D, Lorenz RR, Braun W, Yetman R, Eliachar I, Mayes J. Laryngeal transplantation and 40-month follow-up. *N Engl J Med*. 2001 May 31;344(22):1676-9. doi: 10.1056/NEJM200105313442204. PMID: 11386266.

## NOTA and Final Rule Analysis

The Committee submits this updated guidance on optimizing VCA graft recovery under the authority of 42 US 274 (B)(2)(H), which requires the OPTN to “provide information to physicians and other health professionals regarding organ donation”. This updated guidance is also supported by 42 CFR 121.6(a), which requires any member procuring an organ to “assure that laboratory tests and clinical examinations of potential organ donors are performed to determine any contraindications for donor acceptance, in accordance with policies established by the OPTN”, in addition to 42 CFR 121.6(c), that requires transplant programs to “establish criteria for organ acceptance, and shall provide such criteria to the OPTN and the OPOs with which they are affiliated”. This guidance document provides guidance on laboratory tests, such as screening for infectious disease. It also makes recommendations for clinical examinations, like on-site visual inspection of the donor and intra-operative assessments. Additionally, this updated guidance suggests considering acceptance criteria when identifying and evaluating a potential VCA donor, such as history of organ dysfunction and cold ischemic time.

## Conclusion

This updated guidance document advises on effective practices for identifying and evaluating potential VCA donors, authorizing VCA donation with the donor family, recovery and post-recovery processes, and strategies for honoring donor family and transplant recipient confidentiality when media is involved. Expanding the knowledge and visibility of VCA recovery in the transplant community aims to increase the availability of VCA organs so more VCA candidates can experience the independence and quality of life they desire. The Committee requests transplant programs and OPOs consider the application of these recommendations as they continue to or begin to pursue VCA recovery and transplant.

## Considerations for the Community

1. Are there additional effective practices the Committee should include in these recommendations to the transplant community?
2. What barriers and challenges are keeping the transplant community from becoming more involved with VCA recovery and transplant?
3. What are the experiences of donor families regarding the VCA authorization process?
4. What are the experiences of donor families, recipient families, and recipients with media and public relations strategies?

## Guidance Document

### 1 Guidance on Optimizing VCA Recovery from Deceased Donors<sup>1</sup>

2  
3 Repealed.

### 4 Guidance on Optimizing VCA Recovery (2023 Version)

#### 5 VCA Background

6 VCA transplantation is the transplantation of a composite tissue that may include skin, muscle, bone,  
7 and nerves and that requires blood flow to function after the transplant.<sup>2</sup>

#### 8 The First VCA Transplantations

9 The first successful VCA transplant in the world was a larynx transplant in Cleveland, Ohio in 1998.<sup>3</sup> Later  
10 that year, the first unilateral hand transplant was performed in Lyon, France.<sup>4</sup> This event marked the  
11 recognition that VCAs are the logical next step in reconstructive microsurgery and that surgical  
12 techniques used in conventional reconstructive microsurgery can be successfully utilized in VCA  
13 transplantation. This landmark case ushered in the era of “restorative surgery.” Although “higher” on  
14 the “reconstructive ladder,” by utilizing the exact missing composite tissues from a deceased donor, VCA  
15 transplantation offered the recipient the possibility of fewer reconstructive surgeries and more natural  
16 function and physical appearance. VCA recipients require immunosuppression to prevent immune  
17 rejection of allografts, but in exchange, would be spared the morbidity and possible disfigurement of  
18 conventional reconstructive procedures that required the use of tissue(s) from elsewhere on the  
19 patient’s body. The first successful unilateral hand transplant in the United States, and to date, the  
20 longest lasting in the world, was performed in Louisville, Kentucky in 1999.<sup>5</sup> The recipient lost his  
21 dominant hand in a fireworks accident 13 years earlier.<sup>6</sup>

#### 22 Face Transplantation

23 In 2005, the world's first partial face transplant was performed in Amiens, France. The  
24 recipient underwent surgery to replace her original face, after she was mauled by a dog.<sup>7</sup>

<sup>1</sup> This proposal would repeal the old guidance and replace with this new version. The 2018 version can be found on the OPTN website at [https://optn.transplant.hrsa.gov/media/2503/vca\\_guidance\\_201806.pdf](https://optn.transplant.hrsa.gov/media/2503/vca_guidance_201806.pdf).

<sup>2</sup> OPTN. (2014, November 11). The status of vascularized composite allograft allocation. <https://optn.transplant.hrsa.gov/news/the-status-of-vascularized-composite-allograft-allocation/>

<sup>3</sup> Strome M, Stein J, Esclamado R, Hicks D, Lorenz RR, Braun W, Yetman R, Eliachar I, Mayes J. Laryngeal transplantation and 40-month follow-up. *N Engl J Med.* 2001 May 31;344(22):1676-9. doi: 10.1056/NEJM200105313442204. PMID: 11386266.

<sup>4</sup> J.M. Dubernard, E. Owen, G. Herzberg, *et al.* Human hand allograft: report on first 6 months *Lancet*, 353 (1999), pp. 1315-1320

<sup>5</sup> Jones JW, Gruber SA, Barker JH, Breidenbach WC. Successful hand transplantation. One-year follow-up. Louisville Hand Transplant Team. *N Engl J Med.* 2000 Aug 17;343(7):468-73. doi: 10.1056/NEJM200008173430704. PMID: 10950668.

<sup>6</sup> *Ibid.*

<sup>7</sup> Petruzzo P, Testelin S, Kanitakis J, Badet L, Lengelé B, Girbon JP, Parmentier H, Malcus C, Morelon E, Devauchelle B, Dubernard JM. First human face transplantation: 5 years outcomes. *Transplantation.* 2012 Jan 27;93(2):236-40. doi: 10.1097/TP.0b013e31823d4af6. PMID: 22167048.

25 Three years later in 2008, the first partial face transplant, in the United States, was performed in  
 26 Cleveland, Ohio.<sup>8</sup> The first full face transplant performed in the United States was done in Boston,  
 27 Massachusetts on a construction worker in 2011.<sup>9</sup> The recipient suffered from a high-voltage electrical  
 28 burn.

29 Sixteen years after the hallmark case in France, there have been at least 160 upper extremity and 50  
 30 face VCAs transplants performed from deceased donors worldwide.<sup>10</sup>

### 31 *Uterine Transplantation*

32 Uterus transplantation for women with absolute uterus factor infertility began in the early 2000s.<sup>11</sup> In  
 33 2014, the first baby was born to a uterus transplant recipient in Gothenburg, Sweden.<sup>12</sup> The recipient  
 34 had a congenital uterine agenesis. The first uterus transplant performed in the United States took place  
 35 in Cleveland, Ohio in 2016.<sup>13</sup> The deceased donor transplant failed and was removed within 2 weeks  
 36 post-transplant. That same year the first successful uterus transplant in the United States was  
 37 performed from a living donor in Dallas, Texas. The recipient was born without a uterus and delivered a  
 38 healthy baby boy in 2017.<sup>14</sup> The first baby born after a deceased donor uterus transplant in the United  
 39 States was in Cleveland, Ohio in 2019.<sup>15</sup> As of 2023, there have been more than 100 cases of uterus  
 40 transplantation performed worldwide and 40 cases in the United States.<sup>16</sup> More than 60 babies have  
 41 been born after uterus transplant worldwide including 30 in the United States.<sup>17</sup>

### 42 *Penile Transplantation*

43 The first penis transplantation was performed in 2006 in China.<sup>18</sup> The patient had sustained the loss of  
 44 most of his penis in an accident. Although reported as a surgical success, the graft was removed 15 days  
 45 later. In 2014, the first successful penis transplant was performed in South Africa.<sup>19</sup> The patient had lost

<sup>8</sup> Arno A, Barret JP, Harrison RA, Jeschke MG. Face allotransplantation and burns: a review. J Burn Care Res. 2012 Sep-Oct;33(5):561-76. doi: 10.1097/BCR.0b013e318247eb06. PMID: 22274632; PMCID: PMC3438348.

<sup>9</sup> Singhal, Dhruv M.D.; Pribaz, Julian J. M.D.; Pomahac, Bohdan M.D. The Brigham and Women's Hospital Face Transplant Program: A Look Back. Plastic and Reconstructive Surgery 129(1): p 81e-88e, January 2012. | DOI: 10.1097/PRS.0b013e31823621db

<sup>10</sup> Ibid.

<sup>11</sup> Castellón LAR, Amador MIG, González RED, Eduardo MSJ, Díaz-García C, Kvarnström N, Bränström M. The history behind successful uterine transplantation in humans. JBRA Assist Reprod. 2017 Jun 1;21(2):126-134. doi: 10.5935/1518-0557.20170028. PMID: 28609280; PMCID: PMC5473706.

<sup>12</sup> Brännström M, Johannesson L, Bokström H, Kvarnström N, Mölne J, Dahm-Kähler P, Enskog A, Milenkovic M, Ekberg J, Diaz-Garcia C, Gäbel M, Hanafy A, Hagberg H, Olausson M, Nilsson L. Livebirth after uterus transplantation. Lancet. 2015 Feb 14;385(9968):607-616. doi: 10.1016/S0140-6736(14)61728-1. Epub 2014 Oct 6. PMID: 25301505.

<sup>13</sup> Flyckt R, Kotlyar A, Arian S, Eghtesad B, Falcone T, Tzakis A. Deceased donor uterine transplantation. Fertil Steril. 2017 Mar;107(3):e13. doi: 10.1016/j.fertnstert.2016.12.009. Epub 2017 Feb 8. PMID: 28189293.

<sup>14</sup> Testa G, McKenna GJ, Gunby RT Jr, Anthony T, Koon EC, Warren AM, Putman JM, Zhang L, dePrisco G, Mitchell JM, Wallis K, Klintmalm GB, Olausson M, Johannesson L. First live birth after uterus transplantation in the United States. Am J Transplant. 2018 May;18(5):1270-1274. doi: 10.1111/ajt.14737. Epub 2018 Apr 12. PMID: 29575738.

<sup>15</sup> Flyckt R, Falcone T, Quintini C, Perni U, Eghtesad B, Richards EG, Farrell RM, Hashimoto K, Miller C, Ricci S, Ferrando CA, D'Amico G, Maikhor S, Priebe D, Chiesa-Vottero A, Heerema-McKenney A, Mawhorter S, Feldman MK, Tzakis A. First birth from a deceased donor uterus in the United States: from severe graft rejection to successful cesarean delivery. Am J Obstet Gynecol. 2020 Aug;223(2):143-151. doi: 10.1016/j.ajog.2020.03.001. Epub 2020 Mar 7. PMID: 32151611.

<sup>16</sup> Johannesson L, Richards E, Reddy V, Walter J, Olthoff K, Quintini C, Tzakis A, Latif N, Porrett P, O'Neill K, Testa G. The First 5 Years of Uterus Transplant in the US: A Report from the United States Uterus Transplant Consortium. JAMA Surg. 2022 Sep 1;157(9):790-797. doi: 10.1001/jamasurg.2022.2612. PMID: 35793102; PMCID: PMC9260640.

<sup>17</sup> Ibid.

<sup>18</sup> Weillie H, Jun L, Lichao Z, et al. A preliminary report of penile transplantation. Eur Urol 2006; 50:851–853.

<sup>19</sup> Bateman, C. (2015). World's first successful penis transplant at Tygerberg Hospital. SAMJ: South African Medical Journal, 105(4), 251-252.

46 his penis as a result of a botched circumcision procedure he underwent at age 18. In 2015, the recipient  
 47 announced that he had successfully fathered a child. In 2016 in Boston, a team performed a transplant  
 48 on a 64-year-old man in remission of squamous cell carcinoma.<sup>20</sup> In 2018, The Johns Hopkins Hospital  
 49 performed the world’s first total penis and scrotum transplant.<sup>21</sup> As of 2023 there have been less than  
 50 10 penis transplants worldwide.<sup>22</sup>

51 [OPTN Purview of VCA Organs](#)

52 In 2014, the Health Resources and Services Administration (HRSA) designated VCAs as organs under the  
 53 purview of the OPTN.<sup>23,24</sup> **Table 1-1: VCA types and covered body parts** below lists the VCA types and  
 54 identifies the covered body parts specific to each VCA organ.

<sup>20</sup> Cetrulo, Curtis L. Jr MD\*; Li, Kai MD†; Salinas, Harry M. MD\*; Treiser, Matthew D. MD, PhD\*; Schol, Ilse BS\*; Barrisford, Glen W. MD†; McGovern, Francis J. MD†; Feldman, Adam S. MD, MPH†; Grant, Michael T. MD†; Tanrikut, Cigdem MD†; Lee, Jeffrey H. MD\*; Ehrlichman, Richard J. MD\*; Holzer, Paul W. BS\*; Choy, Garry M. MD, MBA‡; Liu, Raymond W. MD‡; Ng, Zhi Yang MD\*; Lellouch, Alexandre G. MD\*; Kurtz, Josef M. PhD\*; Austen, William G. Jr MD\*; Winograd, Jonathan M. MD\*; Bojovic, Branko MD\*; Eberlin, Kyle R. MD\*; Rosales, Ivy A. MD§; Colvin, Robert B. MD§; Ko, Dicken S. C. MD, FRCSC, FACS\*, †. Penis Transplantation: First US Experience. *Annals of Surgery* 267(5):p 983-988, May 2018. | DOI: 10.1097/SLA.0000000000002241

<sup>21</sup> Nitkin, K. (2018, April 23). *First-Ever Penis and Scrotum Transplant Makes History at Johns Hopkins*. John Hopkins Medicine. <https://www.hopkinsmedicine.org/news/articles/first-ever-penis-and-scrotum-transplant-makes-history-at-johns-hopkins>

<sup>22</sup> Cetrulo, Curtis L. Jr MD\*; Li, Kai MD†; Salinas, Harry M. MD\*; Treiser, Matthew D. MD, PhD\*; Schol, Ilse BS\*; Barrisford, Glen W. MD†; McGovern, Francis J. MD†; Feldman, Adam S. MD, MPH†; Grant, Michael T. MD†; Tanrikut, Cigdem MD†; Lee, Jeffrey H. MD\*; Ehrlichman, Richard J. MD\*; Holzer, Paul W. BS\*; Choy, Garry M. MD, MBA‡; Liu, Raymond W. MD‡; Ng, Zhi Yang MD\*; Lellouch, Alexandre G. MD\*; Kurtz, Josef M. PhD\*; Austen, William G. Jr MD\*; Winograd, Jonathan M. MD\*; Bojovic, Branko MD\*; Eberlin, Kyle R. MD\*; Rosales, Ivy A. MD§; Colvin, Robert B. MD§; Ko, Dicken S. C. MD, FRCSC, FACS\*, †. Penis Transplantation: First US Experience. *Annals of Surgery* 267(5):p 983-988, May 2018. | DOI: 10.1097/SLA.0000000000002241

<sup>23</sup> U.S. Department of Health and Human Services, Final Rule, “Organ Procurement and Transplantation Network.” *Federal Register* 78, no. 128 (July 3, 2013): 40033, <https://www.govinfo.gov/content/pkg/FR-2013-07-03/pdf/2013-15731.pdf>

<sup>24</sup> Implement the OPTN’s Oversight of Vascularized Composite Allografts (VCAs),” Public Comment Proposal, OPTN, accessed May 4, 2023, [https://optn.transplant.hrsa.gov/media/1118/05\\_vca\\_implementation.pdf](https://optn.transplant.hrsa.gov/media/1118/05_vca_implementation.pdf).

**Table 1-1: VCA types and covered body parts<sup>25</sup>**

<u>Type</u>	<u>Covered VCA</u>
<u>Upper limb</u>	<u>Any group of vascularized body parts from the upper limb</u>
<u>Head and neck</u>	<u>Face, larynx, vascularized parathyroid gland, scalp, trachea, vascularized thyroid, and any other vascularized body parts from the head and neck</u>
<u>Abdominal Wall</u>	<u>Abdominal wall, symphysis pubis, and any group of vascularized skeletal elements of the pelvis</u>
<u>Uterus</u>	<u>Uterus</u>
<u>External male genitalia</u>	<u>Penis</u>
<u>Other genitourinary organ</u>	<u>Urinary bladder</u>
<u>Vascularized gland</u>	<u>Vascularized gland</u>
<u>Lower limb</u>	<u>Pelvic structures that are attached to the lower limb and transplanted intact, gluteal region, vascularized bone transfers from the lower extremity, toe transfers, and any group of vascularized body parts from the lower limb</u>
<u>Musculoskeletal composite graft segment</u>	<u>Spine axis, chest wall, and other composite graft of vascularized muscle, bone, nerve, or skin</u>
<u>Spleen</u>	<u>Spleen</u>

56

57 [Benefits of VCA Transplantation](#)

58 The field of VCA transplantation has existed for more than two decades, and the benefits and challenges  
 59 are becoming apparent to larger and wider groups of patients, clinicians, and families. Public attitudes  
 60 toward VCA donation are reported as favorable, and much of this is based on media reports of  
 61 transplant outcomes.<sup>26</sup> There is increased acceptance outside the VCA transplant community that the

<sup>25</sup> OPTN Policy 1.2: Definitions ‘Covered Vascularized Composite Allograft body parts (covered VCAs)’. This language reflects the most recent language approved by the OPTN Board in December of 2021. This language will be implemented pending OMB approval of revised membership forms for Uterus Transplant Programs. See *Establish Membership Requirements for Uterus Transplant Programs* Policy Notice, available at [https://optn.transplant.hrsa.gov/media/gapkro1m/policy-notice\\_establish-membership-requirements-for-uterus-transplant-programs\\_december-2021.pdf](https://optn.transplant.hrsa.gov/media/gapkro1m/policy-notice_establish-membership-requirements-for-uterus-transplant-programs_december-2021.pdf).

<sup>26</sup> Rodrigue, J, Tomich, D, Fleishman, A, and Glaxier, A, “Vascularized Composite Allograft Donation and Transplantation: A Survey of Public Attitudes in the United States”, *American Journal of Transplantation* no 10 (2017), 2687-2695, doi: 10.1111/ajt.14302.



62 therapeutic goal of VCA transplantation is functional restoration and bodily integrity, not only cosmetic  
63 restoration.<sup>27</sup>

64 The benefits of VCA transplantation include increased quality of life and social integration. For example,  
65 the ability to hold someone’s hand, return to near normal appearance after severe trauma, experience  
66 gestation and childbirth, being able to speak, write and smile, and regain independence in activities of  
67 everyday living. The Committee hopes this document provides the transplant community with  
68 knowledge that will contribute to the increased utilization of the precious resources for the patients and  
69 families that can benefit.

## 70 Considerations for the Identification and Initial Evaluation of the 71 Potential VCA Donor

72 As with solid organ transplantation, there are transplant program-specific criteria utilized for the  
73 evaluation of VCA organs from deceased donors; and in the case of uterus transplant, both living and  
74 deceased donors. The criteria and tools used to evaluate potential VCA donors will differ by VCA type.  
75 Minimal criteria for acceptance of all VCAs are based on guidelines for solid organ transplantation, with  
76 additional criteria to ensure the best possible outcomes of the VCA transplant. Additional considerations  
77 are specific to the type of VCA graft needed. The decision to include or exclude VCA from deceased  
78 donors based on these criteria should be left to the individual VCA transplant programs. All deceased  
79 donors should be considered for VCA, and a match run should be generated.

80  
81 Once a match run is generated, communication between the VCA program and the OPO for further  
82 screening, including preliminary virtual and/or flow crossmatch, feasibility, and additional  
83 considerations should occur early in the allocation process. Depending on the VCA type, additional  
84 donor imaging (x-rays, CT scans, vascular ultrasound) may be requested, as well as photographs to  
85 ensure donor-recipient suitability. **Table 1-2: Examples of VCA type-specific evaluation considerations**  
86 below reflects some examples of VCA type specific considerations for the initial evaluation of the  
87 potential VCA donor:

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<sup>27</sup> Caplan, A., “An Ethics Infrastructure for VCA”, presentation at the Evolving Issues of Vascularized Composite Allo-transplantation, Baltimore, MD September 19, 2017.

**Table 1-2: Examples of VCA type-specific evaluation considerations<sup>28</sup>**

	<u>Limb (Upper or Lower, Unilateral or Bilateral)</u>	<u>Head and Neck</u>	<u>Penile</u>	<u>Uterus</u>
<u>Physical attributes</u>	<u>Skin tone, scars, tattoos, distinguishing marks, mechanism of injury, sex/gender, body habitus, height, weight, limb length, laterality (if unilateral)</u>	<u>Tattoos, scars, piercings, skin tone, distinguishing marks, mechanism of injury, sex/gender, anatomic abnormalities</u>	<u>Anatomic abnormalities, distinguishing marks</u>	<u>Anatomic abnormalities</u>
<u>Medical and surgical history considerations</u>	<u>Mechanism of injury/death, vascular access placement, history of limb dysfunction/paralysis</u>	<u>Mechanism of injury/death, history of facial paralysis/dysfunction</u>	<u>Mechanism of injury/death, History of organ dysfunction</u>	<u>Mechanism of injury/death, reproductive history</u>
<u>Additional work-up</u>			<u>Additional infectious testing (e.g., chlamydia, gonococcus, etc.)</u>	<u>Additional infectious testing (e.g., chlamydia, gonococcus, Papanicolaou (PAP), etc.)</u>

89

90 Consistent with solid organ donor evaluation, medical and surgical history review should also specifically  
 91 include: any history of malignancy, current or recent sepsis, disseminated intravascular coagulation  
 92 (DIC), diabetes, 2020 Public Health Service (PHS) Medical and Social Donor Risk Criteria, and other  
 93 factors that may impact form and function of the VCA.

94 After acceptable donor and recipient characteristics are determined, recovery and case-specific needs  
 95 can be discussed. Once VCA authorization is obtained, an OPO team member should speak with the VCA  
 96 surgeon to thoroughly understand VCA recovery. This knowledge is essential to inform the donor’s  
 97 family, funeral home, medical examiner/coroner, and/or law enforcement representatives of the VCA  
 98 donation.

99 Other considerations related to the donor procurement process include:

- 100 • Donor allografts must be recovered and transported within transplant program acceptable limits  
 101 of cold ischemic time. The amount of allowable ischemic time will vary by transplant program,  
 102 type of VCA and size of the allografts. As with other transplanted organs, short ischemic times  
 103 are desired.
- 104 • Transfer to transplant hospital for simultaneous donor/recipient surgeries may be requested.
- 105 • As with the practice in solid organ donation, on-site visual inspection of the donor, prior to  
 106 recovery, and intra-operative assessments are the final components of VCA donor suitability  
 107 evaluation prior to removal of the allografts.
- 108 • Prosthetics/reconstruction of the donor post recovery should be planned to preserve the  
 109 integrity and respect of the donor.

<sup>28</sup> Table 1-2 is not an all-inclusive list of VCA type specific evaluation considerations.

- Evaluation of living donors for VCA will follow *OPTN Policy 14: Living Donation*

Emerging types of VCA transplants may require additional consultations or testing beyond existing standards. OPOs and transplant programs are strongly encouraged to review VCA educational materials on the OPTN Learning Management System in addition to developing protocols and relationships with VCA programs that intend to transplant emerging VCA types.

## Family Considerations

With the advancement of VCA transplants, some donor families can now make an additional gift apart from solid organ and tissue donation. VCA authorization requestors need to be knowledgeable, skilled advocates for VCA donation. OPOs should also develop a standard practice around authorization for VCA donation.

### Preparing Staff for VCA Discussion

Preparation for VCA authorization is key to a successful outcome. VCA transplant surgeons should be engaged with OPO requestors to articulate the need for VCA transplantation and the recovery process. VCA specific considerations should be explained to OPO staff to ensure potential donor families are aware of additional testing, longer operating room time, possible transfer of the donor to a recovery center, reconstruction of the donor site, potential face masks or prosthetics, and funeral home or medical examiner needs. OPOs that have successfully procured VCAs report benefit of rehearsal conversations with OPO staff. These OPOs can also provide suggested scripts and VCA authorization documents. Learning about outcomes of past VCA transplants helps requestors facilitate the approach and become advocates for VCA transplant candidates.

### Authorizing a VCA Donor

When alerted to a donor referral, OPO staff should check the OPTN Computer System to assess if there is a potential recipient that could be a match with the donor. OPO staff are encouraged to contact the VCA transplant program to assess whether there is early interest. If the VCA transplant program representative expresses early interest, the OPO should consider this referral as a potential VCA donor. Further information on the donor should be gathered to assess for contraindications for VCA donation.

Authorization for VCA recovery must be documented carefully and cannot be assumed from general organ donation authorization or registry information. *OPTN Policy 2.14.E: Deceased Donor Authorization Requirement* states that OPOs must document the specific authorization for VCA donation from deceased donors.<sup>29</sup> Effective VCA authorization practices show that VCA authorization should occur after authorization for organ and tissue donation.<sup>30</sup> Further, any discussion on VCA authorization should only occur after identifying a potential recipient. This approach ensures that VCA authorization does not dissuade next-of-kin from life-saving organ donation decisions. Families should be offered the opportunity for VCA donation once a potential recipient has been identified, regardless of whether they have authorized eye or tissue donation. Prospective crossmatching between potential donors and recipients varies between transplant programs and even between different VCA programs at the same transplant hospital. Crossmatch timing and determining if the crossmatch will be virtual or physical must

<sup>29</sup> OPTN Policy 2.14.E: Deceased Donor Authorization Requirement.

<sup>30</sup> OPO Guidance on VCA Deceased Donor Authorization, <https://optn.transplant.hrsa.gov/resources/guidance/opoguidance-on-vca-deceased-donor-authorization/>. Accessed May 19, 2023.

150 be determined between the OPO, histocompatibility lab, and transplant program early in the process.  
151 This is because the crossmatch could determine if VCA donation is offered to a donor family.

152

### 153 *Helping Families Understand the Need for VCA Transplants and Empowering Them to* 154 *Make a Decision*

155 VCA donation is a unique and rare opportunity to make a life-changing donation to a VCA candidate.  
156 OPOs should be conscientious in how they approach VCA donation with different donor families. Donor  
157 families require accurate information about VCA donation opportunities to understand the impact of  
158 the donation, such as the potential benefits the donation could bring to a recipient. When a donor  
159 family feels a connection to the potential recipient, they are more likely to overcome the hesitancy  
160 some have with considering donation of a face, limb, uterus, or penis. That connection between a donor  
161 and recipient represents a facet of VCA donation that is unlike many gifts: VCA transplant offers a  
162 unique continuation of a deceased donor's life through that connection to the potential recipient.  
163 Before sharing any information about a potential recipient, the OPO must abide by all applicable federal  
164 and state privacy laws and should consult their own attorneys and confer with transplant programs prior  
165 to sharing any information.

166

167 Throughout the discussion, the family needs to be assured of the mutual commitment from the OPO  
168 and VCA transplant program to treat the donor with the utmost respect and integrity. Also, the OPO  
169 must disclose the potential for media coverage, potential identification of the recipient by the transplant  
170 hospital, and how the OPO will protect the donor's identity and confidential information.

171

172 Finally, there needs to be transparent communication about the impact of VCA donation on the entire  
173 donation process. Additional testing will be needed to understand the quality of the VCA being  
174 considered and, as a result, additional time may be required to thoroughly evaluate and coordinate the  
175 donation.

176

177 Mock runs can help programs learn what improvements can be made in their recovery processes. These  
178 practice exercises include approaching donor families for VCA authorization and recovery of the graft,  
179 but do not include transplantation of the VCA graft to a living recipient. Transplant programs should  
180 educate the OPO staff, so they are able to convey the importance of donation that promotes the  
181 advancement of the VCA field when making this specific type of authorization ask.

182

### 183 *Recovery Considerations*

184 Coordinating the recovery of VCAs and solid organs for transplant requires collaboration and  
185 communication between the OPO and all transplant hospitals involved in the recovery and transplant of  
186 organs from the deceased donor. Considerations include the timing of VCA recovery and solid organ  
187 recovery, OPO staffing during the recovery, and plans for unexpected donor instability. A conference call  
188 between all recovery teams and the OPO in advance of the recovery procedure allows all parties to  
189 discuss the procurement process and sequence.

190

### 191 *Specialized Considerations for VCA Recovery*

192 Given the complexity of procurement needs associated with VCA transplants, some transplant programs  
193 have opted to move the donor to a specialized or centralized recovery center. The OPO has a lead role in

194 coordinating these activities among various procurement teams, and it is recommended that VCA  
 195 transplant programs discuss needs regarding procurement location as early as possible with OPO staff.

196  
 197 *Timing and Sequence of VCA graft recovery*

198 The addition of VCA recovery to thoracic and/or abdominal organ recovery may add various amounts of  
 199 time to the donor procurement. OPOs and transplant programs should thus plan for recoveries that may  
 200 be of extended length. This will include assigning primary OPO staff and relief staff to the recovery, and  
 201 frequent communication with the donor hospital's operating room when booking the organ recovery.  
 202 While recovery of VCA grafts should be performed whenever possible, non-VCA grafts must be  
 203 prioritized if donor instability intervenes. During the pre-procurement team huddles, it is advisable to  
 204 make plans between procurement teams and OPO staff about the events that will occur should a  
 205 deceased donor become unstable.

206  
 207 This guidance document emphasizes the value of a pre-recovery huddle between all participants,  
 208 inclusive of surgeons and OPO staff. Details of procurement timing, sequence, and preservation should  
 209 be discussed and agreed upon prior to initiation of recovery.

210  
 211 *General Timing Guidelines by VCA Type*

212 Each type of VCA graft has unique criteria for recovery. A brief review of timing considerations for some  
 213 of the VCA types follows. Individual cases may vary significantly from these estimates.

214  
 215 *Upper Limb*

216 The recovery of upper extremities can be performed with or without a tourniquet. The timing of the  
 217 removal of the donor graft may occur prior to or after cross-clamp to optimize the recovery of non-VCA  
 218 organs. In general, recovery procedures take 30 minutes per extremity.<sup>31</sup>

219  
 220 *Facial Allografts*

221 Oftentimes, recoveries from the head and neck precede the thoracic and/or abdominal organ recovery.  
 222 The operating room may be arranged with anesthesia at the foot of the donor instead of the head,  
 223 providing enough space for the VCA recovery team to perform the facial recovery. If a sentinel flap is  
 224 being recovered from the donor's forearm, the arms can be outstretched for this procedure. Elective  
 225 tracheostomy may have to be performed on the donor in advance of the recovery to avoid obstruction  
 226 of the airway during facial recovery. The length of the procedure will be dictated by the size and  
 227 complexity of the graft. Recovery times for facial allografts vary but in general are complex.<sup>32, 33</sup>  
 228 Depending on the type of face allograft, recovery times may vary widely from 2-12 hours. Much of this

<sup>31</sup> Mendenhall SD, Lutfy J, Graham E, Overschmidt B, Levin LS, Neumeister MW. Technique for Rapid Hand Transplant Donor Procurement Through the Elbow. *Hand (N Y)*. 2021 May;16(3):391-396. doi: 10.1177/1558944719863127. Epub 2019 Jul 23. PMID: 31331207; PMCID: PMC8120581.

<sup>32</sup> Bueno J, Barret JP, Serracanta J, Arnó A, Collado JM, Valles C, Colominas MJ, Diez Y, Pont T, Salamero P, Martinez-Ibañez V. Logistics and strategy of multiorgan procurement involving total face allograft. *Am J Transplant*. 2011 May;11(5):1091-7. doi: 10.1111/j.1600-6143.2011.03489.x. Epub 2011 Mar 28. PMID: 21443675.

<sup>33</sup> Brazio PS, Barth RN, Bojovic B, Dorafshar AH, Garcia JP, Brown EN, Bartlett ST, Rodriguez ED. Algorithm for total face and multiorgan procurement from a brain-dead donor. *Am J Transplant*. 2013 Oct;13(10):2743-9. doi: 10.1111/ajt.12382. Epub 2013 Aug 5. PMID: 23915309.

229 recovery can be done prior to the administration of heparin and cross-clamp of thoracic and abdominal  
 230 organs.

231

### 232 Uterus Allografts

233 Multiple uterus recovery approaches have been successful. Most of the uterus dissection occurs prior to  
 234 cross-clamp, in conjunction with the dissection and evaluation of other organs. The sequence of uterus  
 235 dissection can occur at any point but is often performed after dissection of the vital abdominal organs is  
 236 complete. In some circumstances, the uterus has been removed prior to cross-clamp and mimics the  
 237 approach in a living donor hysterectomy. If the uterus is to be removed after cross-clamp, all vital organs  
 238 can be removed first with uterus recovery occurring last. Dissection of the uterus prior to cross-clamp  
 239 can be performed in approximately 2-3 hours. Depending on recovery sequence and order of dissection,  
 240 minimal time or up to 2 hours may be added to the total recovery time for all organs.

241

### 242 Abdominal Wall Allografts

243 In many cases, abdominal wall grafts will be recovered in conjunction with the abdominal organs (liver,  
 244 small bowel). Dissection of the abdominal wall graft can be performed before cross-clamp, and the flap  
 245 can remain connected to blood supply until cross-clamp is performed.<sup>34</sup> Recovery time will also depend  
 246 on the size of the graft, but in general will add 30 minutes to recovery of the abdominal organs.

247

### 248 External Male and Other Genitourinary Allografts

249 As with many VCA grafts, types of genitourinary grafts can vary widely. The graft may include a  
 250 combination of the penis, scrotum, thigh tissue, and lower abdominal wall, or penis alone.<sup>35</sup> In complex  
 251 cases, the recovery can commence prior to cross-clamp to allow more time for dissection of the  
 252 abdominal wall, exposing the blood vessels. At that point, the recovery of other solid organs may  
 253 proceed prior to cross-clamp, if so desired and coordinated with the VCA genitourinary recovery  
 254 team. Once cross-clamp has occurred, procurement teams may proceed removing organs with the VCA  
 255 genitourinary team going last. In this scenario, the total recovery time is minimally impacted by the  
 256 recovery of even a complex urogenital graft.

257

### 258 Tracheal/Esophageal Allografts

259 In the most recent reported recovery of a tracheal allograft, the transplant team simultaneously  
 260 prepared the abdomen for liver procurement. Time from cross-clamp to graft retrieval was 26 minutes.<sup>36</sup>  
 261 Recovery of this graft can occur in conjunction with other organs and does not significantly impact the  
 262 total length of recovery time for all organs.

263

<sup>34</sup> Erdmann D, Atia A, Phillips BT, Mithani SK, Avashia YJ, Hollister BA, Cendales LC, Ravindra KV, Sudan DL. Small bowel and abdominal wall transplantation: A novel technique for synchronous revascularization. Am J Transplant. 2019 Jul;19(7):2122-2126. doi: 10.1111/ajt.15370. Epub 2019 Apr 15. PMID: 30913367.

<sup>35</sup> Lopez CD, Girard AO, Lake IV, Oh BC, Brandacher G, Cooney DS, Burnett AL, Redett RJ. Lessons learned from the first 15 years of penile transplantation and updates to the Baltimore Criteria. Nat Rev Urol. 2023 Jan 10:1–14. Doi: 10.1038/s41585-022-00699-7. Epub ahead of print. PMID: 36627487; PMCID: PMC9838304.

<sup>36</sup> Genden EM, Laitman BM. Human Tracheal Transplantation. Transplantation. 2023 Feb 14. doi: 10.1097/TP.0000000000004509. Epub ahead of print. PMID: 36782283.

264 Summary of Recovery Times for VCA Grafts

265 These estimates are provided only to give an idea how long VCA graft recoveries may take. As in all  
 266 donor recoveries, there will be variability in the timing and sequence of VCA recoveries alongside other  
 267 thoracic and abdominal organs. In some cases, the VCA recovery has occurred before the thoracic  
 268 and/or abdominal organ recovery. In other circumstances, the VCA and thoracic and/or abdominal  
 269 organ recoveries began at the same time with each recovery team given the amount of time necessary  
 270 to complete any warm dissection prior to cross-clamp while the other procurement teams wait.<sup>37</sup> In the  
 271 cases of teams working together, the VCAs may be removed before cross-clamp, then the thoracic  
 272 and/or abdominal organ teams are able to cannulate in preparation for cross-clamp in the standard way.

274 Specialized Needs of the VCA Recovery Team

275 VCA recovery may require specialized surgical equipment not available at all hospitals. If a VCA recovery  
 276 team will be traveling to a donor hospital, the recovery team is responsible for bringing any specialized  
 277 equipment that may be required to complete the recovery. If the VCA recovery is complex, the VCA  
 278 transplant program and OPO should consider the risks and benefits of transporting the VCA donor to the  
 279 transplant hospital where the VCA program is located, or other centralized recovery center as  
 280 mentioned above.

281  
 282 If the VCA team accepting the graft is traveling from farther away, the team may need support with  
 283 ground transportation to and from the donor hospital. If the VCA team is flying-in, the timing of the  
 284 recovery may also impact the duty time of the aircraft crew involved in the trip.

285  
 286 Programs with limited VCA recovery and transplantation experience are encouraged to seek mentorship  
 287 from more seasoned VCA programs. Experienced VCA programs should support the ever-growing VCA  
 288 community by sharing their exemplary practices with recently established programs.

289  
 290 Changes in Donor Hemodynamic Stability

291 If the VCA recovery is planned to proceed prior to cross-clamp and before the thoracic and/or  
 292 abdominal organ recovery, measures should be taken to ensure there is no loss of organs if the donor  
 293 becomes unexpectedly unstable during VCA recovery. The thoracic and/or abdominal organ recovery  
 294 teams should be available at the donor hospital in case instability occurs and the immediate recovery of  
 295 other organs becomes necessary.<sup>38</sup> Preservation solutions for the thoracic and/or abdominal organ  
 296 recovery should be available during the VCA recovery. Blood products for the donor should also be  
 297 available in the donor operating room in the event of blood loss from the VCA recovery and the need for  
 298 transfusion.

299  
 300 Preservation and Packaging

301 OPOs and VCA transplant programs should discuss the plans for use of organ preservation solutions and  
 302 needs for sterile packaging materials. Sterile packaging needs will be determined by the type and size of

<sup>37</sup> Brazio, P, Barth, R, Bojovic, B, Dorafshar, A, Garcia, J, Brown, E, Bartlett, S, and Rodriguez, E, "Algorithm for Total Face and Multiorgan Procurement from a Brain-Dead Donor", American Journal of Transplantation no 13: 2743–, (2013). doi:10.1111/ajt.12382.

<sup>38</sup> Datta, N, Yersiz, H, Kaldas, F, Azari, K, "Procurement strategies for combined multiorgan and composite tissues for transplantation", Current Opinion in Organ Transplantation no 20:121-126, (2015), DOI: .1097/MOT.0000000000000172.

303 grafts being recovered. Separate packaging will be necessary for multiple VCA grafts recovered from the  
304 same donor. As with all other organs, VCAs must be packaged and labeled in accordance with *OPTN*  
305 *Policy 16: Organ and Extra Vessel Packaging, Labeling, Shipping, and Storage*.<sup>39</sup> The labels are printed  
306 from the OPTN Organ Labeling, Packaging and Tracking System.

## 308 Post-Recovery Considerations

309 For head and neck and upper extremity recoveries, the use of prosthetics is strongly recommended if  
310 allowed by the donor family to preserve donor dignity. After recovery, prosthetics must be secured to  
311 prevent them from being dislodged when the donor is moved.

312  
313 OPOs should prepare to document the recovery of VCAs with practices similar to thoracic and/or  
314 abdominal organ recoveries.

### 316 *Funeral Home and Medical Examiner Involvement*

317 OPO communication with the donor family's funeral home of choice is an important step in the VCA  
318 donation process, as it is with the standard organ and tissue donation process. This communication  
319 ensures the funeral home understands that extra care of the donor may be necessary due to anatomical  
320 modifications and the nature of the organ recovery. As VCA donation can extend the organ donation  
321 process, this may impact the funeral arrangements including the funeral director's preparations for  
322 memorial services.

323  
324 Similar concerns apply to medical examiners or coroners who may be investigating the donor's  
325 circumstances of death. Coordination with the medical examiner or coroner following VCA authorization  
326 to ensure there are no restrictions that impact the VCA donation is recommended early in the process.

## 328 Media and Public Relations Strategies

### 329 *Rationale*

330 A media strategy needs to be considered by the transplant program and OPO to protect the privacy of  
331 the recipient, donor, and their families as much as possible. This is to maximize the dissemination of  
332 information while safeguarding the public confidence and transparency for VCA transplantation.

### 333 *Planning*

334 One of the most important first steps, before any media plans are executed, is for the clinicians and  
335 public relations team at the transplant hospital to find out whether the recipient and their family are  
336 comfortable with media attention and interviews, and to what extent. Media attention could include  
337 photography and videography, interviews, and press conferences. This is a dynamic process  
338 throughout the transplant experience, which must be revisited regularly for amendment, as necessary.  
339 Every program is unique, and decisions must be guided by recipient and donor family preferences and  
340 institutional policies.

341 Most of the planning for VCA-related media will fall to the public relations team at the transplant  
342 hospital, with support from the OPO. The transplant hospital should establish a direct line of

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<sup>39</sup> OPTN Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage.



343 communication with the OPO public relations team. This line of communication should be established  
344 as early as possible, ideally before the transplant takes place.

345 A public relations strategy should be developed and include a timeline for any media moments based on  
346 transplantation and subsequent patient milestones. Having this plan in place will mitigate any rushed  
347 announcements and media events. Development of a working group to establish the strategy and  
348 timeline is recommended and should include public relations contacts at all the hospitals involved with  
349 the VCA transplant. This working group should determine whether there will be a press conference and,  
350 if so, who will host and lead the on-site coordination. In most instances, this responsibility would belong  
351 to the transplant program. Ideally, the working group should coordinate any announcements to take  
352 place following the transplant to ensure the public the procedure was a success, the patient is recovering  
353 well, and to provide an added layer of privacy for the recipient, donor, and donor family.

#### 354 [Confidentiality/Anonymity](#)

355 Privacy is paramount for the donor, recipient, and their families. Institutional policies should be followed  
356 and reinforced to protect their identities, if desired. Transplant program staff should counsel the VCA  
357 recipient and recipient family about disclosing information to friends and family and on social media.  
358 Some transplant programs do not release the VCA transplant date as an additional layer of protection.

#