

Briefing to the OPTN Board of Directors on

Establish Membership Requirements for Uterus Transplant Programs

OPTN Vascularized Composite Allograft Transplantation Committee

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Establish Membership Requirements for Uterus Transplant Programs

<i>Affected Policies:</i>	<p>1.2: Definitions</p> <p>2.2: OPO Responsibilities</p> <p>5.4.B: Order of Allocation</p> <p>5.6.A: Receiving and Reviewing Organ Offers</p> <p>5.6.B: Time Limit for Review and Acceptance of Organ Offers</p> <p>18.1: Data Submission Requirements</p> <p>18.2: Timely Collection of Data</p> <p>18.3: Recording and Reporting the Outcomes of Organ Offers</p>
<i>Affected Bylaws:</i>	<p>Appendix J: Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs</p> <p>Appendix N: Definitions</p>
<i>Sponsoring Committee:</i>	Vascularized Composite Allograft Transplantation
<i>Public Comment Period:</i>	August 3, 2021 – September 30, 2021
<i>Board of Directors Date:</i>	December 6, 2021

Executive Summary

The Vascularized Composite Allograft (VCA) Transplantation Committee proposes establishing membership requirements for uterus transplant programs. Currently, VCAs covered by OPTN Policies and Bylaws are categorized into eight types: upper limb, head and neck, abdominal wall, genitourinary organ, vascularized gland, lower limb, musculoskeletal composite graft segment, and spleen. Uterus is included in the genitourinary organ category, along with all other internal and external male and female genitalia and urinary bladder. While OPTN Bylaws contain detailed membership requirements for upper limb, head and neck, and abdominal wall transplant programs, transplant programs performing uterus and other genitourinary organ transplants are subject to more general requirements for “other VCA” transplant programs. These general requirements do not adequately reflect the expertise necessary to safely perform uterus transplants.

Uterus is the most sought-after VCA transplant, with 44 candidates added to the waiting list since 2016. A substantial portion of uterus transplants performed to date (21 out of the 33) were made possible through living donation, but the OPTN has not yet established requirements for transplant programs performing living donor uterus recoveries.¹ The volume of uterus transplants performed in the U.S. is expected to grow, as transplant programs currently performing uterus transplants have been contacted by a significant number of potential recipients and donors interested in uterus transplantation. Given the potential for expansion in the field, the VCA Committee proposes defining uterus as a VCA type separate from other genitourinary organs and establishing more tailored membership requirements for the transplant programs performing uterus transplants and living donor recoveries.

¹ Data as of September 30, 2021, OPTN, accessed October 18, 2021, <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/>

Background

Vascularized composite allografts (VCA) were designated as organs under the purview of the OPTN effective July 3, 2014.^{2,3} At that time, the OPTN Board of Directors approved changes to OPTN Bylaws requiring transplant programs to submit a letter of notification to the OPTN if they intended to perform VCA transplants.⁴ In 2015, 2016, and 2018, the OPTN Board of Directors approved more detailed VCA membership requirements with tailored requirements for head and neck, upper limb, and abdominal wall transplant programs, as these were the most common types of VCA transplants at the time.⁵ The updates to the Bylaws also included general requirements for “other VCA” transplant programs, which included genitourinary organ as well as gland, lower limb, musculoskeletal composite graft segment, and spleen VCA transplant programs. These requirements were implemented in June 2021.⁶ The current types of VCA, the body parts covered under each VCA type, and associated membership requirements are summarized in **Table 1**.

Table 1: Types of VCA and Associated Membership Requirements

Type of VCA	Covered VCA Body Parts	Membership Requirements
Upper limb	Any group of vascularized body parts from the upper limb	Upper limb
Head and neck	Face, larynx, vascularized parathyroid gland, scalp, trachea, vascularized thyroid, and any other vascularized body parts from the head and neck	Head and neck
Abdominal wall	Abdominal wall, symphysis pubis, and any group of vascularized skeletal elements of the pelvis	Abdominal wall
Genitourinary organ	Uterus, internal and external male and female genitalia, and urinary bladder	Other VCA
Vascularized gland	Adrenal and thymus	
Lower limb	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	
Musculoskeletal composite graft segment	Spine axis, chest wall, and other composite graft of vascularized muscle, bone, nerve, or skin	
Spleen	Spleen	

The current genitourinary organ VCA type includes uterus, as well as urinary bladder and internal and external male and female genitalia. Currently, there are nine transplant programs approved by the OPTN

² 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>.

³ “Implement the OPTN’s Oversight of Vascularized Composite Allografts (VCAs),” Public Comment Proposal, OPTN, accessed April 1, 2021, https://optn.transplant.hrsa.gov/media/1118/05_vca_implementation.pdf.

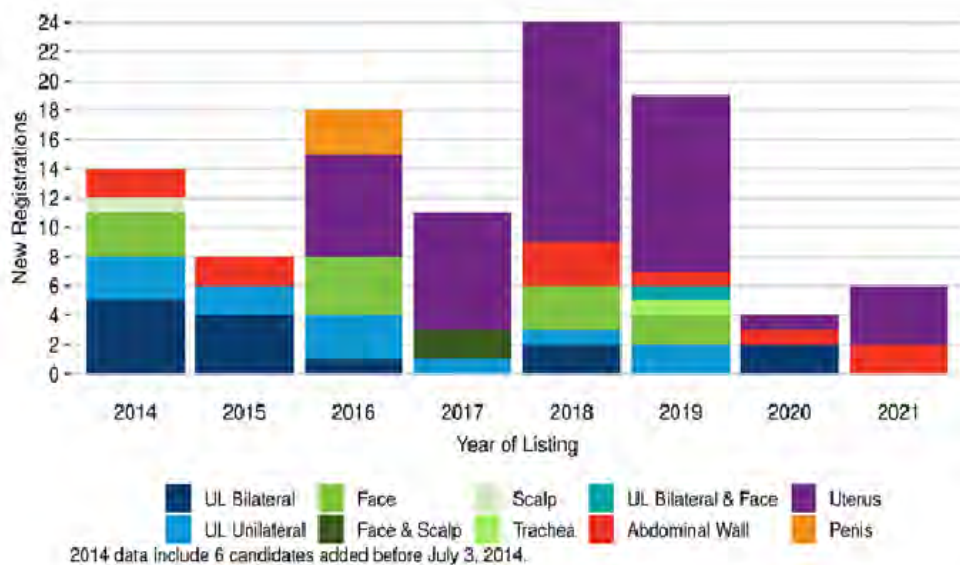
⁴ “Executive Summary of the OPTN Board of Directors Meeting,” June 23-24, 2014, OPTN, accessed April 1, 2021, https://optn.transplant.hrsa.gov/media/1794/executive_summary_06-2014.pdf.

⁵ “Vascularized Composite Allograft Membership Changes,” Notice of OPTN Policy and Bylaw Changes, OPTN, accessed April 1, 2021, https://optn.transplant.hrsa.gov/media/3922/20200731_vca_membershipchanges_policynotice.pdf.

⁶ “Policy Notices,” OPTN, accessed June 24, 2021, <https://optn.transplant.hrsa.gov/governance/policy-notices/>. See “Combined Policy Notice for VCA Membership Requirements” and “Clarification of Policies and Bylaws Specific to Vascularized Composite Allografts” for details.

to perform genitourinary organ transplants.⁷ Two of these programs have each performed a successful penis transplant through deceased donation which benefited candidates whose need arose from both disease and injury.^{8,9} Three of these programs have performed at least 32 uterus transplants since 2016 for patients with absolute uterine factor infertility.¹⁰ These transplants have resulted in at least 21 live births, and most of these transplants (21 of 33, or 64%) were made possible through living uterus donation.¹¹ Another approved program recently opened for referrals for uterus transplantation, and four additional hospitals in the U.S. are building uterus transplant programs.¹² While uterus transplantation has shown promising success to date, eight of the 32 transplanted uterus grafts failed.¹³ While the causes of these graft failures may not be related to the training of personnel at these programs, graft failure is an adverse outcome and its occurrence underscores the importance of ensuring that uterus transplant programs have appropriately trained personnel, particularly as other hospitals open uterus transplant programs. Uterus has become the most sought-after VCA transplant, as over half of the candidates added to the VCA waiting list since 2016 were uterus candidates (**Figure 1**).

Figure 1: Additions to the VCA Waitlist in the U.S.: July 3, 2014 – September 30, 2021¹⁴



Current membership requirements do not include any requirements specific to uterus transplantation, and do not reflect the expertise required for these types of transplants. For example, while expertise in obstetrics and gynecology is critical to achieving a successful uterus transplant resulting in a live birth, the membership requirements do not have a formal role for specialists in obstetrics and gynecology.¹⁵

⁷ "Member Directory," OPTN, accessed June 14, 2021, <https://optn.transplant.hrsa.gov/members/member-directory/>.

⁸ Denise Grady, "Cancer Survivor Receives First Penis Transplant in the United States," *New York Times*, May 16, 2016, <https://www.nytimes.com/2016/05/17/health/thomas-manning-first-penis-transplant-in-us.html>.

⁹ Denise Grady, "'Whole Again': A Vet Maimed by an I.E.D. Receives a Transplanted Penis," *New York Times*, April 23, 2018, <https://www.nytimes.com/2018/04/23/health/soldier-penis-transplant-ied.html>.

¹⁰ OPTN data as of June 11, 2021.

¹¹ OPTN data as of June 24, 2021.

¹² Liza Johannesson, Anji Wall, Andreas Tzakis, et al. "Life underneath the VCA umbrella: perspectives from the United States Uterus Transplantation Consortium," *American Journal of Transplantation* (2020), <https://doi.org/10.1111/ajt.16445>.

¹³ Ibid.

¹⁴ OPTN data as of October 18, 2021.

¹⁵ Liza Johannesson, Anji Wall, Andreas Tzakis, et al. "Life underneath the VCA umbrella: perspectives from the United States Uterus Transplantation Consortium."

Instead, the requirements simply require the primary surgeon to “have assembled a multidisciplinary surgical team that includes specialists necessary to complete the VCA transplant including, for example... obstetrics and gynecology.”¹⁶ Ensuring the appropriate expertise at programs engaged in uterus transplantation is important to protect the safety of uterus transplant recipients and living uterus donors, as well as the safety of children born to uterus recipients. The transplant program must ensure that the recipient’s uterus graft is receiving adequate blood supply not just for graft survival, but also to support a developing fetus throughout pregnancy. Maternal conditions that can impact blood flow to the fetus in non-transplant patients, like chronic hypertension and preeclampsia, are associated with intrauterine growth restriction (IUGR).^{17,18} IUGR can result in stillbirth, preterm delivery and associated risks, and adverse health effects throughout childhood and adulthood.^{19,20}

Uterus transplant programs are currently subject to the same requirements as programs performing transplants of other genitourinary organs like penis, even though different clinical expertise is needed to perform these distinct transplants. Given the low volume of penis and other genitourinary organ transplants to date, the VCA Transplantation Committee (Committee) chose to focus on developing more tailored membership requirements solely for uterus transplant programs. To develop the proposed requirements, the Committee sponsored a workgroup comprised of its members with experience in uterus transplantation, genitourinary surgery, plastic surgery, and development of VCA membership requirements, as well as members of the Membership and Professional Standards Committee (MPSC) and a member of the Living Donor Committee.

The OPTN establishes membership requirements to ensure transplant programs have qualified staff and resources to safely perform transplants. Updating the existing membership requirements to more appropriately reflect the expertise required for uterus transplantation aligns with the OPTN strategic plan goal to promote living donor and transplant recipient safety.²¹ Transplant programs apply for membership to the OPTN by submitting information to demonstrate that the programs meet membership requirements via an application form approved by the Office of Management and Budget (OMB). This information is considered OPTN data collection, and modifying the application forms to reflect updated membership requirements aligns with the OPTN Data Collection Principles to fulfill the requirements of the OPTN Final Rule; determine if institutional members are complying with policy; and ensure patient safety when no alternative sources of data exist.²²

¹⁶ “OPTN Bylaws,” OPTN, accessed June 15, 2021, https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf.

¹⁷ Anju Suhag and Vincenzo Berghella, “Intrauterine Growth Restriction (IUGR): Etiology and Diagnosis,” *Current Obstetrics and Gynecology Reports* 2 (2013): 102-111, doi 10.1007/s13669-013-0041-z.

¹⁸ Hamizah Ismail and Yao-Lung Chang, “Sequelae of Fetal Growth Restriction,” *Journal of Medical Ultrasound* 20 (2012): 191-200, <http://dx.doi.org/10.1016/j.mu.2012.10.005>

¹⁹ Suhag and Berghella, “Intrauterine Growth Restriction,” 103.

²⁰ Terri Levine et al., “Early Childhood Neurodevelopment After Intrauterine Growth Restriction: A Systematic Review,” *Pediatrics* 135, no. 1 (January 2015): 126-141, DOI: <https://doi.org/10.1542/peds.2014-1143>.

²¹ “Strategic Plan 2021-2024,” OPTN, accessed June 24, 2021, <https://optn.transplant.hrsa.gov/media/4632/optn-strategic-plan-2021-2024.pdf>.

²² “Principles for Data Collection,” OPTN, accessed April 2, 2021, <https://optn.transplant.hrsa.gov/members/committees/data-advisory-committee/>.

Purpose

This proposal establishes membership criteria specific to designated uterus transplant programs, including the training and experience of transplant surgeons and transplant physicians in such programs, to promote living uterus donor and uterus transplant recipient safety.

Proposal for Board Consideration

The Committee proposes updating OPTN Policies and Bylaws to establish uterus as a type of VCA separate from other genitourinary organs. Additionally, the Committee proposes updating OPTN Bylaws to establish more tailored membership requirements for uterus transplant programs, including requirements for the primary surgeon and for hospitals performing living donor recovery of uteri. The Committee also proposes establishing a new role for a primary obstetrician-gynecologist within uterus transplant programs, in addition to the primary physician role. Finally, the Committee proposes a small number of administrative changes to clarify the current membership requirements for “other VCA” transplant programs.

Establish “Uterus” As a Separate VCA Type

Currently, the genitourinary organ category of covered VCAs is defined as including “uterus, internal and external male and female genitalia, and urinary bladder.”²³ The Committee proposes splitting the “genitourinary organ” VCA type into three separate categories of VCA: uterus, external male genitalia, and other genitourinary organs, as outlined below in **Table 2**.

Table 2: Splitting “Genitourinary Organ” VCAs into Separate Categories

Type:	Covered VCA(s)
Uterus	Uterus, cervix, and vagina
External male genitalia	Penis and scrotum
Other genitourinary organ	Internal male genitalia; external and internal female genitalia other than uterus, cervix, and vagina; and urinary bladder

Since VCA transplant program membership requirements are defined by VCA type, splitting the genitourinary organ category into separate VCA types allows the OPTN to define different membership requirements for each type. The Committee initially explored developing membership requirements more broadly for genitourinary organ transplant programs but found that the training and expertise needed to perform uterus transplants is distinct from the training and expertise needed to perform penis transplants. Generally, surgeons performing uterus transplants are trained in gynecologic surgery or abdominal organ transplant surgery,²⁴ whereas the surgeons who led the teams that have performed

²³ “Covered Vascularized Composite Allograft body parts (covered VCAs),” Policy 1.2 Definitions, OPTN Policies, accessed June 28, 2021, https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf.

²⁴ Nobuhiko Suganuma, Ayako Hayashi, and Iori Kisu et al., “Uterus transplantation: Toward clinical application in Japan,” *Reproductive Medicine and Biology* 16 (2017): 305-313, DOI: 10.1002/rmb2.12048.

penis transplants in the U.S. were trained in plastic surgery and reconstructive urology.^{25,26} No other types of genitourinary organ transplantation have been performed in the U.S. since 2014.²⁷ Given the distinct training pathways for these fields of surgery, the Committee decided it is more appropriate from a patient safety standpoint to define the transplant program membership requirements more narrowly than for the broader field of genitourinary organ transplantation as a whole.

Uterus

This proposal focuses on requirements for uterus transplant programs because it is the most common type of genitourinary organ transplantation, with 33 transplants performed as of September 2021.²⁸ Additionally, the volume of uterus transplants performed is expected to grow, given significant interest from both potential recipients and potential living donors.²⁹ For the purposes of OPTN Policy, the Committee proposes defining “uterus” as encompassing the uterus, cervix, and vagina, as the cervix and upper part of the vagina (known as the vaginal cuff) are generally included as part of the uterus transplant.³⁰

Male External Genitalia

The Committee is not proposing membership requirements tailored to penis transplantation at this time since only two penis transplants have been performed in the U.S. as of October 2021.³¹ However, the Committee proposes distinguishing “male external genitalia” as a separate VCA type because these transplants have occurred and the associated transplant programs remain active members of the OPTN, demonstrating a level of clinical research, planning, and execution not yet observed for other genitourinary organs. The term “male external genitalia” was selected to encompass the penis and the scrotum, as one of the penis transplants performed to date included the scrotum as part of the allograft.³² Requiring transplant programs to submit a separate membership application for male external genitalia organ transplant will improve the OPTN’s ability to monitor interest and development in this area of transplantation. This will also help inform the Committee as to when developing requirements specific to these programs are needed.

Other Genitourinary Organ

The Committee proposes grouping other genitourinary organ transplants (to include internal male genitalia; external and internal female genitalia other than uterus, cervix, and vagina; and urinary bladder) into a VCA type called “other genitourinary organ” because clinical practice in this area is not as developed as for uterus transplantation or male external genitalia transplantation. While isolated cases

²⁵ “Penis Transplant Program,” Johns Hopkins Medicine, accessed June 25, 2021, https://www.hopkinsmedicine.org/dev/xtest_kara/reconstructive-transplant/penis-transplant.html#ourteam.

²⁶ Noah R. Brown, “MGH Performs Nation’s First Penile Transplant,” Massachusetts General Hospital, accessed June 25, 2021, <https://giving.massgeneral.org/mass-general-performs-penile-transplant/>.

²⁷ OPTN data as of October 18, 2021.

²⁸ *Ibid.*

²⁹ Living Donor Committee Meeting Summary, May 12, 2021, OPTN, accessed June 24, 2021, https://optn.transplant.hrsa.gov/media/4656/20210512_ldc_summary.pdf.

³⁰ BP Jones, NJ Williams, S Saso, et al., “Uterine transplantation in transgender women,” *BJOG* 126 (2019): 152-156, doi:10.1111/1471-0528.15438.

³¹ Based on OPTN data as of October 18, 2021.

³² Denise Grady, “‘Whole Again’: A Vet Maimed by an I.E.D. Receives a Transplanted Penis,” *The New York Times*, April 23, 2018, <https://www.nytimes.com/2018/04/23/health/soldier-penis-transplant-ied.html>.

of testicular transplant^{33,34} and ovarian transplant³⁵ have been documented in the U.S., these cases predate the implementation of VCA transplants as organ transplants under the purview of the OPTN, and the Committee is not aware of transplant programs pursuing these types of transplants at this time. One benefit of separating “other genitourinary organ” transplants from uterus and male external genitalia transplants is that transplant programs interested in performing such transplants would be required to submit a separate membership application to the OPTN. In contrast, under current requirements, transplant programs interested in performing uterus, male external genitalia, or any other genitourinary organ transplant all apply for OPTN membership as genitourinary organ transplant programs. Accordingly, requiring transplant programs to submit a separate membership application for unique and rare types of genitourinary organ transplant will improve the OPTN’s ability to monitor interest and development in this area of transplantation.

“Other VCA” Transplant Programs

This proposal does not include any changes to membership requirements for VCA types that are subject to the membership requirements for “other VCA” transplant programs. Vascularized gland, lower limb, musculoskeletal composite graft segment, and spleen transplant programs will still be required to comply with the membership requirements for “other VCA” transplant programs. External male genitalia and other genitourinary organ transplant programs will also continue to follow the membership requirements for “other VCA” transplant programs. The Committee will continue to monitor developments in the field of VCA and consider more tailored membership requirements for these transplant programs once more of these transplants have been performed in the United States.

Primary Surgeon Requirements

Across organs, the OPTN primary surgeon requirements can generally be divided into three main categories: (1) general requirements, (2) board certification or alternative (foreign equivalent), and (3) other training and experience. The Committee proposes new requirements across each of these categories for the primary surgeon of a uterus transplant program.

General Requirements

The following requirements currently apply to the primary surgeon of any transplant program, regardless of organ type, as outlined in OPTN *Bylaws Appendices E-J*:³⁶

- The surgeon must have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital’s state or jurisdiction
- The surgeon must be accepted onto the hospital’s medical staff, and be on-site at the hospital

³³ Sherman J. Silber, “Transplantation of a human testis for anorchia,” *Fertility and Sterility* 30, no. 2 (August 1978): 181-187, [https://www.fertstert.org/article/S0015-0282\(16\)43457-6/pdf](https://www.fertstert.org/article/S0015-0282(16)43457-6/pdf).

³⁴ Denise Grady, “Surgeons Transplant a Testicle From One Brother to His Twin,” *The New York Times*, December 6, 2019, <https://www.nytimes.com/2019/12/06/health/testicles-transplant.html>.

³⁵ Sherman J. Silber, Gedis Grudzinskas, and Roger G. Gosden, “Successful Pregnancy after Microsurgical Transplantation of an Intact Ovary,” *New England Journal of Medicine* 359 (2008): 2617-2618, <https://www.nejm.org/doi/full/10.1056/NEJMc0804321>.

³⁶ OPTN Bylaws, OPTN, available at https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf.

- The surgeon must have documentation from the hospital’s credentialing committee that it has verified the surgeon’s state license, training, and continuing medical education, and that the surgeon is currently a member in good standing of the hospital’s medical staff

The Committee proposes including these requirements for the primary surgeon of a uterus transplant program.

Currently, the primary surgeon of any VCA transplant program must also have observed at least two multi-organ procurements, which must be documented in a log that includes the date of procurement and Donor ID.³⁷ This requirement was established in 2015 with the intent to ensure that VCA primary surgeons, particularly those trained in disciplines other than organ transplantation, have some understanding of the logistics involved with a multiple organ donor; the priority of solid organ procurement relative to VCA procurement; and clinical challenges that may arise from a multi-organ donor that destabilizes in the operating room.³⁸ The Committee proposes adding more flexibility to this requirement for the primary surgeon of a uterus transplant program so that a surgeon can meet this requirement if they have either observed or completed two multi-organ procurements within the last five years, or completed at least one deceased donor uterus procurement as primary surgeon within the last five years. The Committee added the option for completion of multi-organ procurements so that abdominal organ transplant surgeons who perform multi-organ procurements themselves can meet this requirement, rather than having to separately observe such procurements as performed by other surgeons. Additionally, the Committee added the option for completion of one deceased donor uterus procurement so that surgeons who perform deceased donor uterus recoveries can meet this requirement without separately having to observe multi-organ procurements.

Board Certification or Alternative

Surgeons involved in uterus transplantation come to the field from two main disciplines: abdominal organ transplantation and gynecology/reproductive medicine.³⁹ Accordingly, the Committee proposes including all of the board certification options that are available to the primary surgeons of abdominal organ (kidney, liver, intestine, and pancreas) transplant programs, which are:

- American Board of Surgery
- American Board of Urology
- American Osteopathic Board of Surgery
- Royal College of Physicians and Surgeons of Canada

The Committee also proposes including the American Board of Obstetrics and Gynecology (ABOG) and the American Osteopathic Board of Obstetrics and Gynecology (AOBOG) as board certification options to encompass surgeons trained in gynecology and reproductive medicine. The Accreditation Council for Graduate Medical Education (ACGME) is the primary organization in the U.S. that accredits residencies and fellowships,⁴⁰ and the ACGME recognizes certification from either ABOG or AOBOG as appropriate

³⁷ Ibid.

³⁸ “Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs,” OPTN, Briefing Paper, June 2015.

³⁹ Saganuma et al., “Uterus transplantation,” 308.

⁴⁰ “ACGME, AOA, and AACOM Usher in New Era of Single Accreditation for Graduate Medical Education,” Accreditation Council for Graduate Medical Education, July 1, 2020, <https://www.acgme.org/Newsroom/Newsroom-Details/ArticleID/10568/ACGME-AOA-and-AACOM-Usher-in-New-Era-of-Single-Accreditation-for-Graduate-Medical-Education/>.

qualifications for program directors and faculty members of graduate medical education programs in obstetrics and gynecology.⁴¹

A surgeon must have current certification from at least one of these six boards in order to serve as the primary surgeon of a uterus transplant program, or meet alternative requirements (foreign equivalent). The alternative requirements are consistent with those available to the primary surgeons of abdominal organ and thoracic organ transplant programs:⁴²

- The surgeon must be ineligible for American board certification
- The surgeon must provide a plan for continuing education that is comparable to American board maintenance of certification, as outlined in the OPTN Bylaws
- The surgeon must provide two letters of recommendation to the OPTN

For uterus transplant programs, these letters of recommendation must be from the directors of designated VCA, kidney, liver, intestine, or pancreas transplant programs not employed by the applying hospital, as the Committee anticipates that surgeons qualified to lead uterus transplant programs will have worked with either existing VCA transplant programs (including those currently performing uterus transplants) or abdominal organ transplant programs, and the directors of such programs can attest to the qualifications of those surgeons.⁴³

Training and Experience

The Committee proposes five different pathways for a surgeon to demonstrate they have the training and experience to serve as the primary surgeon of a uterus transplant program:

- ACGME-approved gynecologic oncology fellowship
- Other gynecologic oncology fellowship that meets certain criteria
- Abdominal organ (kidney, liver, intestine, or pancreas) transplant fellowship
- Clinical experience with uterus transplantation
- Clinical experience with radical hysterectomies

Gynecologic oncology fellowships

ACGME provides oversight of obstetrics and gynecology fellowships, including fellowships in gynecologic oncology.^{44,45} Gynecologic oncology is the subspecialty of obstetrics and gynecology that is most applicable to uterus transplantation because it entails significant surgical experience with relevant

⁴¹ “ACGME Program Requirements for Graduate Medical Education in Obstetrics and Gynecology,” Accreditation Council for Graduate Medical Education, accessed June 25, 2021, https://www.acgme.org/Portals/0/PFAAssets/ProgramRequirements/220_ObstetricsAndGynecology_2020.pdf?ver=2020-06-29-162338-630.

⁴² OPTN Bylaws, OPTN, available at https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf.

⁴³ “Addressing the Term ‘Foreign Equivalent’ in OPTN/UNOS Bylaws,” Public Comment Proposal, OPTN, accessed June 24, 2021, https://optn.transplant.hrsa.gov/media/1186/0815-06_Foreign_Equivalent.pdf.

⁴⁴ J. Stuart Ferriss, Steve Rose, and Bunja Rungruang, et al., “Society of Gynecologic Oncology recommendations for fellowship education during the COVID-19 pandemic and beyond: Innovating programs to optimize trainee success,” *Gynecologic Oncology* 160, no. 1 (January 2021): 271-278, DOI: 10.1016/j.ygyno.2020.10.009.

⁴⁵ “Obstetrics and Gynecology: Program Requirements and FAQs,” Accreditation Council for Graduate Medical Education, accessed May 21, 2021, <https://www.acgme.org/Specialties/Program-Requirements-and-FAQs-and-Applications/pfcatid/12/Obstetrics%20and%20Gynecology/>.

procedures, particularly hysterectomies.⁴⁶ Since accreditation of obstetrics and gynecology fellowship programs has transitioned to ACGME from the ABOG relatively recently,^{47,48} the Committee also proposes a separate pathway for surgeons who have completed other gynecologic oncology fellowship programs that meet certain criteria. These criteria are:

- The fellowship program is at a hospital that has inpatient facilities, operative suites and diagnostic treatment facilities, outpatient facilities, and educational resources.
- The fellowship program is at an institution that has a proven commitment to graduate medical education.
- The fellowship program director must have current certification in the sub-specialty by the American Board of Surgery, ABOG, or AOBOG.
- The fellowship program should have at least 2 physician faculty members with gynecologic surgery experience and current medical licensure who are actively involved in the instruction and supervision of fellows during the time of accredited education.
- The program has the resources, including adequate clinical facilities, laboratory research facilities, and appropriately trained faculty and staff, to provide research experience.

This pathway is similar to the pathways available to the primary surgeons of upper limb and head and neck transplant programs who completed non-ACGME fellowships in relevant fields, as outlined in *Section J.2.A.2 Additional Primary Surgeon Requirements for Upper Limb Transplant Programs* and *Section J.2.B.2 Additional Primary Surgeon Requirements for Head and Neck Transplant Programs* of the OPTN Bylaws.⁴⁹

Abdominal organ transplant fellowships

The Committee proposes that any surgeon who meets the training and experience requirements to be the primary surgeon for an abdominal organ (kidney, liver, intestine, or pancreas) transplant program has the requisite experience to fill this role at a uterus transplant program, based on the clinical similarities between abdominal organ and uterus transplantation, and the experiences of abdominal organ transplant surgeons who have entered the field of uterus transplantation.⁵⁰ Accordingly, this requirement can be met if the surgeon has completed either a formal 2-year surgical transplant fellowship or clinical experience as outlined in *Appendices E, F, or G* of the OPTN Bylaws.

Clinical experience

Surgeons who have not completed the fellowships described above may still qualify to serve as the primary surgeon of a uterus transplant program if they can demonstrate clinical experience with uterus transplantation or radical hysterectomies. Radical hysterectomy is the most comparable clinical

⁴⁶ "Subspecialty Procedural Volume Guidelines," ACGME Review Committee for Obstetrics and Gynecology, accessed May 28, 2021, <https://www.acgme.org/Portals/0/PFAssets/ProgramResources/SubspecialtyProceduralVolumeGuidelines.pdf?ver=2018-04-12-103522-560>.

⁴⁷ "For Residents," American Board of Obstetrics and Gynecology, accessed May 28, 2021, <https://www.abog.org/program-resources/for-residents>.

⁴⁸ "Subspecialty Procedural Volume Guidelines," ACGME Review Committee for Obstetrics and Gynecology.

⁴⁹ OPTN Bylaws, OPTN, available at https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf.

⁵⁰ OPTN Vascularized Composite Allograft Transplantation Committee, Genitourinary Membership Requirements Workgroup, OPTN, Meeting Summary, May 17, 2021, accessed June 25, 2021, https://optn.transplant.hrsa.gov/media/4666/20210517_vca_gu_membership_summary_final.pdf.

procedure to uterus graft retrieval.⁵¹ A simple hysterectomy removes the uterus and the cervix, whereas a radical hysterectomy removes the uterus, cervix, the upper part of the vagina, and tissues next to the uterus (the parametria and the uterosacral ligaments).⁵²

To qualify based on experience in uterus transplantation, the surgeon must have completed at least two uterus transplants within the last five years as primary surgeon or co-surgeon, and the surgeon must have completed pre-operative assessments and post-operative care for a minimum of 90 days after surgery. To qualify based on experience in radical hysterectomies, the surgeon must have completed at least 15 radical hysterectomies within the last five years as the primary surgeon. In each case, the surgeon must submit a detailed log documenting the experience.

Between 2016 and September 2021, 33 uterus transplants were performed in the U.S. across three transplant centers,⁵³ and at least 65 uterus transplants have been performed worldwide since 2000.⁵⁴ Given the relatively low volume of transplants both within the U.S. and around the world compared to other fields of transplantation, the Committee decided that completion of two uterus transplants was appropriate as it may be difficult for surgeons interested in starting new programs to achieve a higher case volume.⁵⁵ This is also why the Committee felt that demonstrating this experience in either the role of primary surgeon or co-surgeon would be appropriate, as it would be challenging for a surgeon interested in starting a new program to gain this experience in the role of primary surgeon.

The Committee also wanted to offer an option for other surgeons with relevant clinical experience to be able to fill the role of the primary surgeon, which is why the option for experience in radical hysterectomies was included. The term “radical hysterectomy” is used by the ACGME in their procedural volume guidelines for gynecologic oncology fellowship programs.⁵⁶ While the procedural volume guidelines are not patient minimum requirements for individual fellows, the Committee used these guidelines as a reference to select 15 as the appropriate number of radical hysterectomies to demonstrate the experience needed to serve as the primary surgeon of a uterus transplant program. The Committee decided it is appropriate to require that the surgeon has completed this experience as the primary surgeon, since this pathway is primarily intended to be open to experienced surgeons who were not trained in the U.S., as well as experienced surgeons who trained in the U.S. but completed a minimally invasive surgery fellowship rather than a gynecologic oncology fellowship.⁵⁷

⁵¹ Myra K. Feldman, Sara A. Hunter, and Uma C. Perni, et al., “New Frontier: Role of the Radiologist in Uterine Transplantation,” *RadioGraphics* 40, no. 1 (January-February 2020): 291-302, <https://doi.org/10.1148/rg.2020190123>.

⁵² “Surgery for Cervical Cancer,” American Cancer Society, accessed May 25, 2021, <https://www.cancer.org/cancer/cervical-cancer/treating/surgery.html>.

⁵³ OPTN data as of October 18, 2021

⁵⁴ Iana Malasevskaia and Ahmed A. Al-Awadhi, “A New Approach for Treatment of Women With Absolute Uterine Factor Infertility: A Traditional Review of Safety and Efficacy Outcomes in the First 65 Recipients of Uterus Transplantation,” *Cureus* 13, no. 1 (2021): e12772, doi:10.7759/cureus.12772.

⁵⁵ OPTN Vascularized Composite Allograft Transplantation Committee, Genitourinary Membership Requirements Workgroup, OPTN, Meeting Summary, February 17, 2021, accessed May 25, 2021, https://optn.transplant.hrsa.gov/media/4468/20210217_vca_gu_membership_summary.pdf.

⁵⁶ “Subspecialty Procedural Volume Guidelines,” ACGME Review Committee for Obstetrics and Gynecology.

⁵⁷ OPTN Vascularized Composite Allograft Transplantation Committee, OPTN, Meeting Summary, June 9, 2021, <https://optn.transplant.hrsa.gov/members/committees/vca-committee/>.

Medical Expert Support

The Committee acknowledges that performing successful uterus transplants requires a multidisciplinary team with skills and expertise beyond those which the primary surgeon and primary physician are required to possess.⁵⁸ Accordingly, the Committee proposes requiring the primary surgeon to show proof of collaboration with experts in these fields:

- Abdominal organ (kidney, liver, intestine, or pancreas) transplant surgery
- Gynecologic oncology
- Maternal fetal medicine
- Neonatology
- Reproductive endocrinology/infertility
- Urology
- Uterus transplant surgery

The primary surgeon must provide the name of the expert in each field who collaborates with the uterus transplant program. The primary surgeon and primary physician may fulfill some of these requirements if they are experts in these fields. The intent is to ensure that all necessary expertise is available to the transplant program. For example, if both the primary surgeon and primary physician are trained in abdominal organ transplant surgery, this will require that they show proof of collaboration with experts in uterus transplant surgery. The Committee believes that these requirements for medical expert support will ensure that uterus transplant programs have the appropriate expertise, while also allowing flexibility for uterus transplant programs in how they build their multidisciplinary teams.

The goal of uterus transplantation is to achieve the live birth of a child and requires several steps.⁵⁹ For uterus recipients, pregnancy is achieved through in vitro fertilization (IVF), so uterus transplant programs must work with reproductive endocrinology/infertility experts to assist with embryo generation and implantation. Experts in gynecologic oncology and urology are needed to prepare for and to perform the uterus transplant surgery, and to assist with any intraoperative or postoperative surgical complications that may arise. Experts in maternal fetal medicine are needed to care for the uterus recipient throughout a high risk pregnancy. Infants born to uterus recipients are generally delivered prematurely (at less than 37 weeks gestation) via planned cesarean section, so experts in neonatology must be available to assist in care of the newborn infants.

Transplant programs⁶⁰ must show evidence of collaborative involvement with experts in the fields of radiology, infectious disease, pathology, immunology, anesthesiology, histocompatibility, immunogenetics, and, as appropriate, pediatrics, so uterus transplant programs will also be subject to these requirements.⁶¹ Transplant programs, including uterus transplant programs, must also have on staff professionals to coordinate the psychosocial needs of transplant candidates, recipients, living donors, and their families.^{62,63} These existing requirements combined with the requirements proposed

⁵⁸ Practice Committee of the American Society of Reproductive Medicine, "American Society for Reproductive Medicine position statement on uterus transplantation: a committee opinion," *Fertility and Sterility* 110, no.4 (September 2018): 605-610, <https://doi.org/10.1016/j.fertnstert.2018.06.017>.

⁵⁹ Malasevskaja and Al-Awadhi, "A New Approach for Treatment of Women With Absolute Uterine Factor Infertility," e12772.

⁶⁰ Unless otherwise designated as a transplant program under 42 C.F.R. §121.9(a)(1) or (a)(3).

⁶¹ 42 C.F.R. §121.9(a)(2)

⁶² 42 CFR §121.9 (a)(2)(vii)

⁶³ OPTN Bylaws Section D.9.E Mental Health and Social Support, OPTN, available at

by the Committee largely align with the composition of the uterus transplantation team as recommended by the American Society for Reproductive Medicine in 2018.⁶⁴

The Committee considered requiring uterus transplant programs to have a team member with experience in microvascular surgery or to show proof of collaboration with experts in microvascular surgery. Uterus transplant programs are currently designated as genitourinary organ transplant programs and are subject to membership requirements for “other VCA” transplant programs, which include a requirement to have a team member with microvascular experience such as replantation, revascularization, free tissue transfer, and major flap surgery. Some committee members recommended retaining such a requirement due to documented uterus transplant complications related to vascular anastomoses.^{65,66,67,68} However, members involved in uterus transplantation recommended not to include this requirement, as the uterus transplants performed in the U.S. to date have primarily been performed by abdominal organ transplant surgeons and gynecologic surgeons,⁶⁹ whereas surgeons with more in-depth microvascular experience tend to be trained in plastic surgery.⁷⁰ Furthermore, the uterus transplant surgery is technically similar to other abdominal organ transplant surgeries, and the OPTN does not require abdominal organ transplant programs to demonstrate experience in microvascular surgery. Members felt that requiring uterus transplant programs to show proof of collaboration with experts in abdominal organ transplant surgery would ensure that these programs have adequate expertise to perform vascular anastomoses. Accordingly, the Committee opted not to include a requirement related to microvascular surgery for uterus transplant programs.

Primary Physician Requirements

Currently, the requirements to serve as the primary physician of a VCA transplant program are the same for all eight types of VCA transplant programs.⁷¹ These requirements offer three pathways to qualify as the primary physician:

1. Currently serving as the primary surgeon or primary physician at a designated transplant program
2. Fulfills the requirements of a primary surgeon or primary physician at a designated transplant program according to the OPTN Bylaws
3. Is a physician who meets all of the following requirements:

https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf.

⁶⁴ Practice Committee of the American Society of Reproductive Medicine, “American Society for Reproductive Medicine position statement on uterus transplantation,” 606.

⁶⁵ G. Testa, E.C. Koon, L. Johannesson, et al., “Living Donor Uterus Transplantation: A Single Center’s Observations and Lessons Learned From Early Setbacks to Technical Success,” *American Journal of Transplantation* 17 (2017): 2901-2910, DOI: 10.1111/ajt.14326.

⁶⁶ I. Kisu, Y. Kato, and H. Obara, et al., “Emerging problems in uterus transplantation,” *BJOG: An International Journal of Obstetrics and Gynaecology* 125 (2018): 1352-1356, DOI: 10.1111/1471-0528.15230.

⁶⁷ Giuliano Testa and Liza Johannesson, “The Value of a Nulliparous Uterus,” *Transplantation* 105, no. 5 (May 2021): 958-959, DOI: 10.1097/TP.0000000000003347.

⁶⁸ Malasevskaia and Al-Awadhi, “A New Approach for Treatment of Women With Absolute Uterine Factor Infertility: A Traditional Review of Safety and Efficacy Outcomes in the First 65 Recipients of Uterus Transplantation,” e12772.

⁶⁹ Suganuma et al., “Uterus transplantation,” 308.

⁷⁰ Erica Y. Xue, Sebastian Winocour, and Nicholas Cen et al., “Certification and Accreditation in Plastic Surgery Subspecialty Training,” *Plastic and Reconstructive Surgery – Global Open* 8, no. 7 (July 2020): e2893, DOI: 10.1097/GOX.0000000000002893.

⁷¹ OPTN Bylaws, OPTN, available at https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf.

- a. Holds an M.D., D.O. or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction
- b. Is accepted onto the hospital's medical staff and is on-site at the hospital
- c. Has documentation from the hospital's credentialing committee that it has verified the physician's state license, board certification, training, and transplant continuing medical education, and that the physician is currently a member in good standing of the hospital's medical staff
- d. Has completed an approved transplant fellowship in a medical or surgical specialty, according to the requirements in OPTN Bylaws *Appendices E* through *I*
- e. Has current board certification by the American Board of Medical Specialties or the Royal College of Physicians and Surgeons of Canada (or meets the requirements of the alternate pathway if ineligible for American board certification)

When these VCA membership requirements were developed in 2015-2016, the intent was to ensure that the primary transplant physician would have the requisite expertise to manage recipient care, including immunosuppression,⁷² particularly since the primary surgeon of a VCA transplant program might be a surgeon trained in a discipline other than transplant, such as plastic surgery, oral surgery, or hand surgery. The Committee proposes retaining all of these pathways for uterus transplant programs, since the primary surgeon of a uterus transplant program might be trained in gynecologic surgery. If the individual qualifies as the primary physician for a uterus transplant program because they are currently serving as the primary surgeon or primary physician at another designated transplant program, they would need to list the program for which they are a primary. If the individual is not currently a primary but fulfills requirements to be a primary surgeon or physician, a program application would be required to document how the individual fulfills requirements. This is consistent with the requirements as listed in the current VCA membership application.⁷³

Primary Obstetrician-Gynecologist Requirements

The Committee proposes adding a new requirement specific to uterus transplant programs to designate a primary obstetrician-gynecologist (OB/GYN) in addition to the primary surgeon and primary physician. OB/GYN expertise is critical to the success of uterus transplant programs to monitor the uterus recipient's health through evaluation, IVF, uterus transplantation, embryo implantation, and a high-risk pregnancy, to successful delivery of an infant.⁷⁴ However, the current membership requirements for "other VCA" transplant programs, which apply to uterus transplant programs, do not include a formal role for this expertise. The Committee recognizes that OB/GYNs have a key leadership role in uterus transplant programs in managing patient safety and believes that formally designating a primary OB/GYN will ensure that uterus transplant programs have adequate expertise in obstetrics and gynecology.

The Committee initially considered allowing an OB/GYN to fill the primary physician role, in which case the transplant program would have been obligated to designate a transplant physician or surgeon to

⁷² "Align VCA Transplant Program Membership Requirements with Requirements of Other Solid Organ Transplant Programs," Briefing Paper, OPTN, accessed May 27, 2021, https://optn.transplant.hrsa.gov/media/2524/vca_boardreport_201806_membership.pdf.

⁷³ "OPTN Membership Application for Vascularized Composite Allograft (VCA) Transplant Programs," OPTN, accessed May 27, 2021, <https://unos.org/wp-content/uploads/unos/FORM-OPTN-Membership-App-VCA.pdf>.

⁷⁴ Malasevskaia and Al-Awadhi, "A New Approach for Treatment of Women With Absolute Uterine Factor Infertility," e12772.

assist with recipient care, particularly immunosuppression management. Members of the MPSC emphasized the importance of ensuring that uterus transplant programs have expertise in transplantation, particularly immunosuppression, as well as expertise in obstetrics and gynecology, and recommended designating an OB/GYN separate from the primary physician, who is generally responsible for managing immunosuppression for transplant recipients.⁷⁵ The Committee supported this approach to better improve the OPTN's ability to ensure that uterus transplant programs have the appropriate expertise, rather than simply requiring the primary surgeon to demonstrate proof of collaboration with experts in obstetrics and gynecology.

To qualify as the primary OB/GYN of a uterus transplant program, the OB/GYN must meet general requirements that apply to the primary surgeon and primary physician of any OPTN-approved transplant program:

- Have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction
- Be accepted onto the hospital's medical staff, and is on-site at this hospital
- Have documentation from the hospital's credentialing committee that it has verified the obstetrician-gynecologist's state license, board certification, training, and continuing medical education, and that the obstetrician-gynecologist is currently a member in good standing of the hospital's medical staff

Additionally, the OB/GYN must have current board certification in obstetrics and gynecology by ABOG, AOBOG, or the Royal College of Physicians and Surgeons of Canada (or meet the requirements of the alternate pathway if ineligible for American board certification).

The Committee considered including a residency requirement for the primary OB/GYN, but since OB/GYNs must successfully complete their residency in order to achieve board certification, the Committee felt it would be redundant to include residency as a separate requirement.⁷⁶

Living Donor Recovery Requirements

OPTN Bylaws include additional requirements for transplant programs that perform living donor recovery of livers and kidneys. Since 21 living donor uterus transplants have been performed in the U.S. to date⁷⁷ and this number is expected to grow, the Committee proposes establishing similar requirements for transplant programs that perform living donor recovery of uteri to ensure that programs have the appropriate qualifications to protect the safety of living donors. These requirements include that the uterus recovery hospital must:

- Be a designated uterus transplant program
- Have protocols and resources in place for performing living donor assessments
- Have clinical resources available to assess the medical condition of and specific risks to the living donor

⁷⁵ Membership and Professional Standards Committee Meeting Summary, May 25, 2021, OPTN, accessed June 24, 2021, https://optn.transplant.hrsa.gov/media/4683/20210525_mpsc_meeting_summary.pdf.

⁷⁶ OPTN Vascularized Composite Allograft Transplantation Committee Genitourinary Membership Requirements Workgroup, May 24, 2021, Meeting Summary, OPTN, accessed June 28, 2021, https://optn.transplant.hrsa.gov/media/4689/20210524_vca_gu_membership_summary.pdf.

⁷⁷ OPTN data as of October 18, 2021.

- Have the clinical resources to perform a psychosocial evaluation of the living donor
- Have an independent living donor advocate (ILDA) who is not involved with the evaluation or treatment decisions of the potential recipient, and is a knowledgeable advocate for the living donor

These requirements align with OPTN *Policy 14: Living Donation* as well as a proposal recently implemented by the OPTN Board of Directors to update *Policy 14* to include all living donors, including living uterus donors.⁷⁸

The Committee also proposes requirements for the living donor uterus surgeon, similar to current requirements for the living donor liver surgeon.⁷⁹ The Committee proposes that the uterus recovery hospital must have on-site at least one surgeon who has demonstrated experience as the primary surgeon, co-surgeon, or first assistant in completion of at least 10 radical hysterectomies, living donor uterus recoveries, or some combination thereof, within the last five years. The Committee also proposes that the uterus recovery surgeon have demonstrated experience, in the last five years, as the primary or co-surgeon in completion of:

- at least two living donor uterus recoveries or
- one living donor uterus recovery, at least one deceased donor uterus procurement, and at least 1 direct observation of living donor uterus recovery, or
- At least 2 deceased donor uterus procurements and at least 2 direct observations of living donor uterus recoveries.

All procedures must be documented in a detailed log.

Initially, the Committee proposed that the living donor uterus surgeon must have at least two living donor uterus recoveries, but after discussing public comment feedback stating that this may be too much of a barrier for new programs, they agreed that it would be appropriate to open the requirement to include deceased donor uterus procurements as long as the surgeon also observed living donor uterus recoveries to make the requirement more inclusive while still gaining experience with living donation. These requirements will ensure that the living donor uterus surgeon has adequate clinical experience in removing uteri from living patients, and that the surgeon has experience preserving blood vessels in uterus recovery needed for uterus transplantation.⁸⁰

Administrative Changes

The Committee proposes a small number of administrative changes to clarify membership requirements for “other VCA” transplant programs. *Section J.2.D Additional Primary Surgeon Requirements for Other VCA Transplant Programs* of the OPTN Bylaws⁸¹ requires the primary surgeon to have assembled a multidisciplinary team that includes specialists necessary to complete the VCA transplant. This section

⁷⁸ “Modify Living Donation Policy to Include Living VCA Donors,” OPTN, accessed May 25, 2021, <https://optn.transplant.hrsa.gov/governance/public-comment/modify-living-donation-policy-to-include-living-vca-donors/>.

⁷⁹ OPTN Bylaws, OPTN, available at https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf.

⁸⁰ OPTN Vascularized Composite Allograft Transplantation Committee Genitourinary Membership Requirements Workgroup, May 24, 2021, Meeting Summary, OPTN, accessed June 28, 2021, https://optn.transplant.hrsa.gov/media/4689/20210524_vca_gu_membership_summary.pdf.

⁸¹ OPTN Bylaws, OPTN, available at https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf.

also requires that the team include a team member with microvascular experience, and that the team demonstrate detailed planning that is specific for the type of VCA transplant the program will perform.

The Committee proposes moving the requirement for the team to demonstrate detailed planning just after the requirement for the surgeon to assemble a multidisciplinary team, rather than after the requirement for microvascular experience, to clarify that it is the multidisciplinary team established by the primary surgeon that must demonstrate detailed planning. Additionally, the Committee proposes clarifying that the team member with microvascular experience must submit a log that documents “at least two” of these procedures, as this section does not currently specify the number of procedures required. Since these changes do not substantively change the requirements for “other VCA” transplant programs, these programs would not have to re-apply for OPTN membership as a result of this proposal.

The Committee proposes including a technical correction to add clarity to existing language in Policies 2.2 OPO Responsibilities, 18.1 Data Submission Requirements, 18.2 Recording and Reporting the Outcomes of Organ Offers, and 18.3 Recording and Reporting the Outcomes of Organ Offers by removing the word “covered” from “covered VCA” references because these are “exclusionary” versus “inclusionary” policies.

OPTN Data Collection Development Process

The Committee sought input and guidance from the OPTN Data Advisory Committee (DAC) during the development of this proposal to improve data quality and to ensure that proposed changes to OPTN data collection (via the membership application) are aligned with the OPTN Principles for Data Collection.⁸² The DAC evaluated the potential data burden of the proposal and endorsed the project, acknowledging that the primary purpose of collecting data regarding adherence to updated membership requirements is to ensure that uterus transplant programs are qualified to perform these unique transplants and to protect the safety of donors and recipients involved in these transplants.⁸³

Overall Sentiment from Public Comment

The proposal was released for public comment from August 3, 2021 to September 30, 2021. During that time, it received 181 responses, nine of which also had a substantive written comment. Following is a summary of the overall sentiment for the proposal, as well as a summary of feedback on certain themes of the proposal. The major areas that the OPTN received feedback on were:

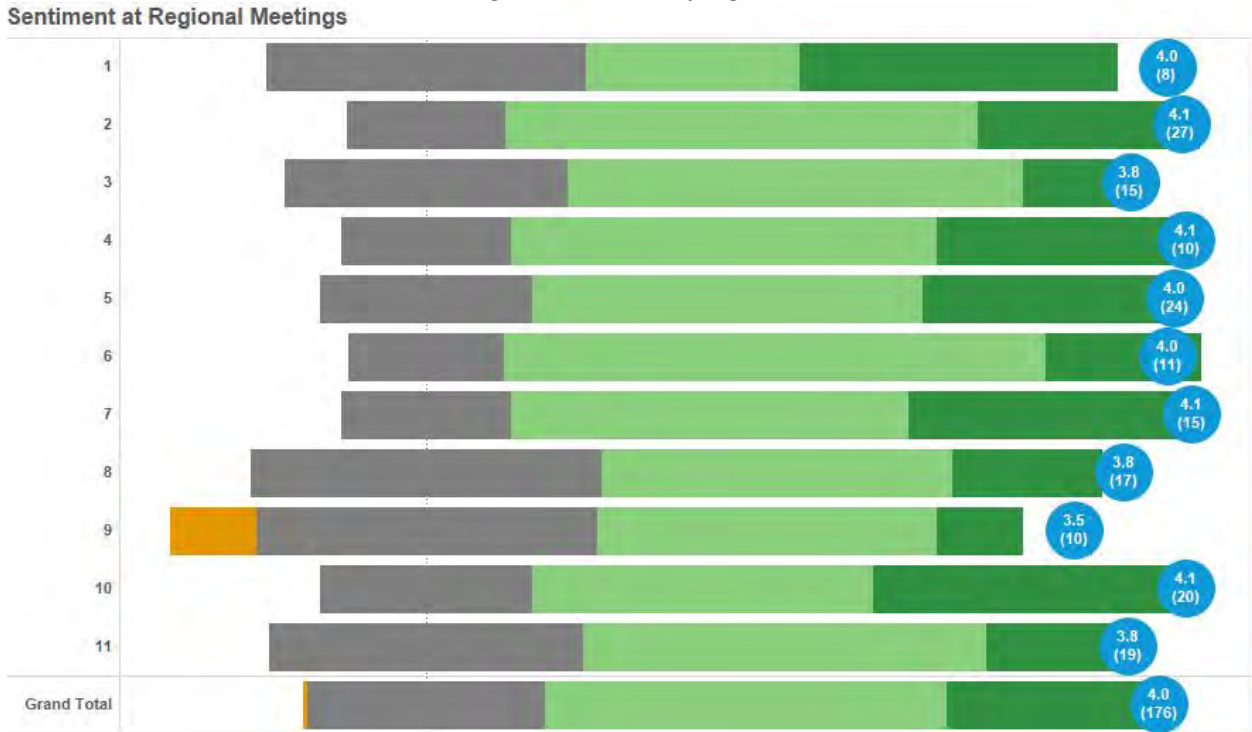
- Living Donor Surgeon Requirements
- Genitourinary Program Types
- Inclusion of a primary obstetrician-gynecologist and other medical expertise

The proposal was supported across all Regions, with an average sentiment score of 4/5 on the Likert sentiment scale. **Figure 2** shows the sentiment by Region, which was supportive overall.

⁸² “Principles for Data Collection,” OPTN, accessed April 2, 2021, <https://optn.transplant.hrsa.gov/members/committees/data-advisory-committee/>.

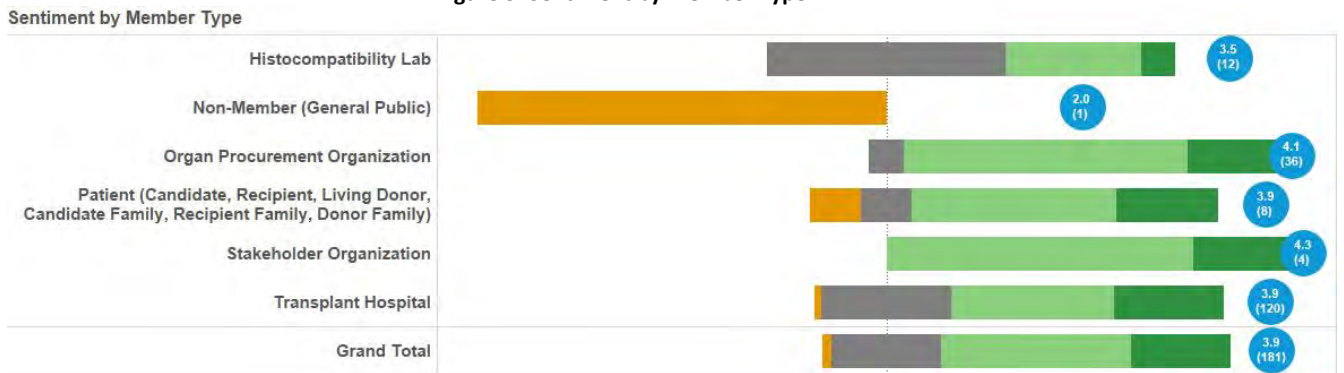
⁸³ OPTN Data Advisory Committee, OPTN, Meeting Summary, April 12, 2021, accessed May 25, 2021, https://optn.transplant.hrsa.gov/media/4585/20210412_dac_meeting_summary.pdf.

Figure 2: Sentiment by Region⁸⁴



The next graphic, **Figure 3**, shows the sentiment received at regional meetings and through the OPTN Public Comment website by member type, with the highest support coming from organ procurement organizations (OPO) and stakeholder organizations. Overall, the proposal was generally supported with four sentiments of opposition submitted. The feedback that was in opposition included not being supportive of the OPTN’s role in VCA transplantation and general concern over uterus transplantation with emphasis on how living donors and recipients may be effected by a transplant that is considered life-enhancing and not life-saving.

Figure 3: Sentiment by Member Type⁸⁵



⁸⁴ Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Dark green indicates strongly support, light green indicates support, grey indicates neutral/abstain, and orange indicates oppose. Sentiment for regional meetings only includes attendees at that regional meeting. Region 6 uses the average score for each institution. The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.

⁸⁵ Ibid.

Living Donor Surgeon Requirements

Feedback on the proposed requirements for a primary living donor uterus surgeon included the possibility that the requirements may be too prohibitive for new uterus transplant programs. Both the American Society of Transplant Surgeons (ASTS) and the American Society of Transplantation (AST) recommended that the requirement of performing at least two living donor recoveries as primary or co-surgeon be revised to be more inclusive since it may not be feasible for a potential uterus living donor surgeon since there are very few programs performing living donor uterus recoveries. An individual submitted that the risks associated with living donation of a uterus is too high for the benefit. The National Catholic Bioethics Center, the National Catholic Partnership on Disability, the Catholic Medical Association, and the National Association of Catholic Nurses, USA also felt that living donors face significant risk and may regret the donation later in life. However, the OPTN Living Donor Committee supported the requirements as written citing that those involved in living donor uterus transplants should be the ones to determine an acceptable number of procedures. The Committee considered the feedback and felt it would be appropriate to revise the initially proposed living donor uterus surgeon requirements in a way that maintains the level of skill needed to perform these procedures with the intention of not being an extreme barrier to new uterus transplant programs.

Genitourinary Program Types

Feedback was received on the proposed types of genitourinary organ programs which included how the programs are split into three types, uterus, external male genitalia, and other genitourinary organ. Both ASTS and AST suggested that instead of splitting programs into the proposed types that “internal and external male genitalia” and “internal and external female genitalia” be considered since the expertise required for female genitourinary procedure types may fall under what is being proposed for uterus transplant programs. However, the Committee noted that the proposed program types are slightly based on anatomic division, but more so the practicality of what is currently being performed and the Committee would revisit requirements for the other types as they become more common.⁸⁶ Due to the unique nature of each genitourinary VCA graft, it is likely that the personnel for proposed program types would not have the experience necessary to perform all the genitourinary VCA transplants that would be included in the suggested broader categories should they become more common.

Inclusion of a Primary Obstetrician-Gynecologist and Other Medical Expertise

Feedback on the inclusion of another primary role in addition to a primary surgeon and physician included the expertise of the primary obstetrician-gynecologist (OB/GYN) and if the third role was necessary. The Hospital of the University of Pennsylvania suggested that uterus programs maintain alignment with the two primary roles (surgeon and physician) required in other designated transplant programs since it is possible for the expertise of an OB/GYN to be embodied within the two primary roles. The National Catholic Bioethics Center, the National Catholic Partnership on Disability, the Catholic Medical Association, and the National Association of Catholic Nurses, USA supported establishing the new role of primary OB/GYN, but felt there should be more specific requirements for neonatologist expertise. AST submitted that either the primary surgeon or OB/GYN should have

⁸⁶ Vascularized Composite Allograft Transplantation Committee Meeting Summary, June 9, 2021, OPTN, accessed October 12, 2021, https://optn.transplant.hrsa.gov/media/4723/20210609_vca-committee-meeting-summary_final.pdf

requirements specific to training in immunology, transplant medicine, or have collaboration with a local transplant team. This proposal includes a requirement that the surgeon show proof of collaboration with an expert in abdominal organ (kidney, liver, intestine, or pancreas) transplant surgery. Also, a VCA transplantation program must be at a designated transplant hospital that has approval for at least one transplant program in addition to the VCA program designation.⁸⁷ The MPSC suggested that the medical expert support requirements specify what qualifies individuals for those roles and that the Committee define “demonstrates collaboration” so that the MPSC knows what should be submitted by a member to prove they have met the requirement. The Committee considered the provided feedback and discussed aligning with other supportive roles such as the Medical Expert Support required for transplant hospitals found in *Appendix D.4.D* of the OPTN Bylaws and indicating the individual by name on the membership applications. The Committee felt that the process for medical expert support proposed for uterus transplant programs should not differ from what is already in place for transplant program support.⁸⁸

Compliance Analysis

NOTA and OPTN Final Rule

The Committee submits this proposal under the authority of the National Organ Transplant Act, which requires the OPTN to “establish membership criteria,”⁸⁹ and per the OPTN Final Rule, which states that the OPTN Board of Directors shall be responsible for developing policies regarding the training and experience of transplant surgeons and transplant physicians in designated transplant programs.⁹⁰ Furthermore, the OPTN Final Rule requires designated transplant programs⁹¹ to have “adequate resources to provide transplant services to its patients.”⁹² This proposal establishes membership criteria for designated uterus transplant programs, including the requirements for primary surgeons and primary physicians at those programs, and describes the resources necessary to safely provide transplant services to uterus candidates and donors.

Finally, the OPTN Final Rule states that the OPTN shall “identify all covered body parts in any policies specific to vascularized composite allografts.”⁹³ The OPTN meets this requirement by listing the body parts covered by VCA-specific policies and bylaws in OPTN Policy 1.2: Definitions.⁹⁴ This proposal modifies this list of covered VCA body parts to designate “uterus” as a type of VCA distinct from other genitourinary organs in order to establish membership criteria specific to uterus transplant programs.

OPTN Strategic Plan

Promote living donor and transplant recipient safety:

⁸⁷ OPTN Bylaws, OPTN, available at https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf.

⁸⁸ Vascularized Composite Allograft Transplantation Committee Meeting Summary, June 9, 2021, OPTN, accessed October 12, 2021, https://optn.transplant.hrsa.gov/media/4723/20210609_vca-committee-meeting-summary_final.pdf.

⁸⁹ 42 USC §274 (b)(2)(B).

⁹⁰ 42 CFR §121.4 (a)(4).

⁹¹ Unless otherwise designated as a transplant program under 42 C.F.R. §121.9(a)(1) or (a)(3).

⁹² 42 CFR §121.9(a)(2).

⁹³ 42 CFR §121.4(e)(3).

⁹⁴ “List covered body parts for VCA,” OPTN, accessed June 24, 2021, <https://optn.transplant.hrsa.gov/governance/public-comment/list-covered-body-parts-for-vca/>.

This policy and bylaw proposal intends to establish membership requirements for uterus transplant programs to provide fundamental safety for uterus recipients and living donors.

Implementation Considerations

Member and OPTN Operations

The OPTN and transplant hospitals that perform genitourinary organ transplants would need to take action to implement this proposal, but this proposal is not anticipated to affect the operations of organ procurement organizations or histocompatibility laboratories.

Operations affecting the OPTN

This proposal would require the submission of official OPTN data that are not presently collected by the OPTN via membership application forms. The OPTN Contractor has agreed that data collected pursuant to the OPTN's regulatory requirements in the OPTN Final Rule will be collected through OMB approved data collection forms.⁹⁵ Therefore, after OPTN Board approval, the proposed data collection changes will be submitted for OMB approval under the Paperwork Reduction Act of 1995. This will require a revision of the OMB-approved data collection instruments, which may impact the implementation timeline.

Once approved by OMB, the revisions would be applied to the OPTN VCA membership application and the revised membership application would be posted. Guidance on how to complete the revised membership application would be provided to members, and the OPTN would be responsible for managing review and approval of new membership applications.

Operations affecting Transplant Hospitals

This proposal would require existing genitourinary organ transplant programs to re-apply for membership to the OPTN as a uterus, external male genitalia, or other genitourinary organ transplant program to demonstrate compliance with the updated membership requirements. These changes would add some administrative burden for genitourinary organ transplant programs with the goal of promoting living donor and transplant recipient safety as more hospitals look to start uterus transplant programs. The Committee hopes that these requirements would also serve as a guide for hospitals that are interested in starting uterus transplant programs and ultimately increase the number of hospitals performing these transplants.

Projected Fiscal Impact

This proposal is projected to have a fiscal impact on the OPTN and transplant hospitals that perform uterus transplants, but it is not anticipated to have any fiscal impact on organ procurement organizations or histocompatibility laboratories.

⁹⁵ 42 CFR §121.3(b)(2) "To apply for membership in the OPTN: A transplant hospital shall provide to the OPTN the name and address of the hospital, a list of its transplant programs by type of organ..."; and §121.9(b) "To apply to be a designated transplant program, transplant programs shall provide to the OPTN such documents as the OPTN may require which show that they meet the requirements of §121.9(a) (1), (2), or (3)."

Projected Impact on the OPTN

Policy and Community Relations (PCR) staff hosted a workgroup to establish specific requirements for VCA programs performing uterus transplants and living donor uterus recoveries. This proposal would create separate requirements for uterus transplant programs, in contrast to current policy where uterus transplant programs are subject to the general VCA requirements. The development process included meetings, policy development, Committee and leadership calls, writing, and outreach.

UNOS IT estimates it will require 843 hours for the development of this proposal, which includes the creation of uterus program requirements within the membership system and subsequent testing. A small number of implementation hours are required from PCR, Communications, and Member Quality. These departments will work closely in conjunction with one another to provide member education, develop new membership applications, and facilitate the application process with members and the MPSC.

A very small ongoing effort is anticipated by IT to maintain membership systems, and by PCR to review the status of designated VCA transplant programs. Member Quality anticipates a small ongoing effort to facilitate the key personnel change application process for uterus, external male genitalia, and other genitourinary organ transplant programs when programs report key personnel changes.

Projected Impact on Transplant Hospitals

Transplant hospitals that perform any type of genitourinary organ transplants (uterus, male external genitalia, or other) would need to re-apply for membership to the OPTN. This may entail 20 to 40 hours of work for uterus transplant programs to complete the application and compile supporting documentation to demonstrate training and experience, but the burden is expected to be lower for male external genitalia and other genitourinary organ transplant programs, particularly if these programs do not have any changes to key personnel since they last applied for membership to the OPTN. While there are no new requirements proposed for male external genitalia and other genitourinary organ transplant programs, programs that perform these transplants would be asked to re-apply for membership in order to notify the OPTN as to how their program(s) should be classified since the broader “genitourinary organ” transplant program membership type would no longer exist. For example, a current genitourinary organ transplant program that performs only uterus transplants would need to submit a new application for a uterus transplant program, whereas a current genitourinary organ transplant program that performs both uterus transplants and male external genitalia transplants would need to submit a separate application for each program type.

Transplant hospitals with uterus transplant programs may also have to hire a new ILDA or transplant coordinator to support uterus transplantation, but these costs may be marginal if existing staff can absorb the workload. Since all hospitals must have other solid organ transplant programs in order to establish a designated VCA transplant program, including uterus, transplant hospitals performing uterus transplants may already have many of the resources needed to support these updated requirements. The burden of re-applying for membership to the OPTN is balanced by the benefit of ensuring appropriate expertise at these transplant programs to protect patient safety.

Post-implementation Monitoring

Member Compliance

Member Quality staff would facilitate the MPSC's review of uterus, external male genitalia, and other genitourinary organ transplant program applications to determine compliance with these proposed bylaws. Upon implementation, Member Quality staff would also facilitate the MPSC's review of key personnel change applications to ensure ongoing compliance with the Bylaws when changes to a uterus, external male genitalia, or other genitourinary organ transplant program's key personnel occur.

Policy Evaluation

This policy will be formally evaluated approximately 1-year post-implementation. The following metrics, and any others subsequently requested by the Committee, will be evaluated as data become available to compare performance before and after policy implementation:

- Number of patient safety events reported for uterus candidates/recipients or living donors
- Number of approved uterus transplant programs
- Number of uterus candidates on the waiting list
- Number of uterus transplants performed, overall and by donor type

Conclusion

This proposal would establish membership requirements specific to uterus transplant programs to ensure that such programs have the appropriate expertise to safely perform these transplants. This proposal would also distinguish uterus transplants as a type of VCA distinct from male external genitalia transplants (to include penis and scrotum) and other genitourinary organ transplants.

Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary. The [...] signifies language in the current Policy that is not presented here for the purposes of brevity and will not be affected by the proposal.

1 1.2 Definitions

2 The definitions that follow are used to define terms specific to the OPTN Policies.

3 C

4 Covered Vascularized Composite Allograft body parts (covered VCAs)

5 The body parts listed below are covered VCAs. Covered VCAs are categorized by type as follows:

Covered VCA(s)	Type:
Any group of vascularized body parts from the upper limb	Upper limb
Face, larynx, vascularized parathyroid gland, scalp, trachea, vascularized thyroid, and any other vascularized body parts from the head and neck	Head and neck
Abdominal wall, symphysis pubis, and any group of vascularized skeletal elements of the pelvis	Abdominal wall
Uterus, internal and external male and female genitalia, and urinary bladder	Genitourinary organ
<u>Uterus, cervix, and vagina</u>	<u>Uterus</u>
<u>Penis and scrotum</u>	<u>External male genitalia</u>
<u>Internal male genitalia; external and internal female genitalia other than uterus, cervix, and vagina; and urinary bladder</u>	<u>Other genitourinary organ</u>
Adrenal and thymus	Vascularized gland
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	Lower limb

Covered VCA(s)	Type:
Spine axis, chest wall, and other composite graft of vascularized muscle, bone, nerve, or skin	Musculoskeletal composite graft segment
Spleen	Spleen

6

7 2.2 OPO Responsibilities

8 The host OPO is responsible for *all* of the following:

9

10 [...]

11

12 11. Executing the match run and using the resulting match for each deceased donor organ allocation.

13 The previous sentence does not apply to ~~covered~~ VCA transplants; instead, members must allocate
 14 covered VCAs according to *Policy 12.2: VCA Allocation*.

15

16 [...]

17

18 5.4.B Order of Allocation

19 The process to allocate deceased donor organs occurs with these steps:

20

- 21 1. The match system eliminates candidates who cannot accept the deceased donor based on
- 22 size or blood type.
- 23 2. The match system ranks candidates according to the allocation sequences in the organ
- 24 allocation policies.
- 25 3. OPOs must first offer organs to potential transplant recipients (PTRs) in the order that the
- 26 PTRs appear on a match run.
- 27 4. If no transplant program on the initial match run accepts the organ, the host OPO may give
- 28 transplant programs the opportunity to update candidates' data with the OPTN. The host
- 29 OPO must re-execute the match run to allocate the organ.
- 30 5. Extra vessels allocated with an organ but not required for its transplant can be shared
- 31 according to *Policy 16.6.A: Extra Vessels Use and Sharing*.
- 32 6. Members may export deceased donor organs to hospitals in foreign countries only after
- 33 offering these organs to all PTRs on the match run. Members must submit the *Organ Export*
- 34 *Verification Form* to the OPTN prior to exporting deceased donor organs.

35

36 This policy does not apply to ~~covered~~ VCA transplants; ~~instead~~, members must allocate covered
 37 VCAs according to *Policy 12.2: Covered VCA Allocation*.

38

39 5.6.A Receiving and Reviewing Organ Offers

40 Transplant hospitals must view organ offers and respond to these offers through the match
 41 system. The previous sentence does not apply to ~~covered~~ VCA transplants.

42

43 The transplanting surgeon at the receiving transplant hospital is responsible for ensuring the
 44 medical suitability of organs offered for transplant to potential recipients, including whether
 45 deceased donor and candidate blood types (and donor subtype, when used for allocation) are
 46 compatible or intended incompatible.

47
 48 **5.6.B Time Limit for Review and Acceptance of Organ Offers**

49 This policy does not apply to expedited liver offers as outlined in *Policy 9.10.B: Expedited Liver*
 50 *Offers* or to VCA transplants.

51
 52 A transplant hospital has a total of one hour after receiving the initial organ offer notification
 53 to access the deceased donor information and submit a provisional yes or an organ offer
 54 refusal.

55
 56 Once the host OPO has provided all the required deceased donor information according to
 57 Policy 2.11: Required Deceased Donor Information, with the exception of organ anatomy
 58 and recovery information, the transplant hospital for the initial primary potential transplant
 59 recipient must respond to the host OPO within one hour with *either* of the following:

- 60
- 61 • An organ offer acceptance
- 62 • An organ offer refusal

63 All other transplant hospitals who have entered a provisional yes must respond to the host
 64 OPO within 30 minutes of receiving notification that their offer is for the primary potential
 65 transplant recipient with *either* of the following:

- 66
- 67 • An organ offer acceptance
- 68 • An organ offer refusal

69
 70 The transplant hospital must respond as required by these timeframes or it is permissible
 71 for the host OPO to offer the organ to the transplant hospital for the candidate that appears
 72 next on the match run.

73
 74 ~~This policy does not apply to covered VCA transplants.~~

75
 76 **18.1 Data Submission Requirements**

77 Members must report accurate data to the OPTN using standardized forms according to *Table 18-1*
 78 below. Members are responsible for providing documentation upon request to verify the accuracy of all
 79 data that is submitted to the OPTN through the use of standardized forms.

80

81

Table 18-1: Data Submission Requirements⁹⁶

The following member:	Must submit the following materials to the OPTN:	Within:	For:
Recovery Hospitals	<i>Living donor feedback</i>	The time prior to donation surgery	Each potential living donor organ recovered at the hospital This does not apply to covered VCA donor organs
Recovery Hospitals	<i>Living donor registration (LDR)</i>	60 days after the recovery hospital submits the <i>living donor feedback</i> form	Each living donor organ recovered at the hospital This does not apply to covered VCA donor organs
Recovery Hospitals	<i>Living donor follow-up (LDF)</i>	60 days after the six-month, 1-year, and 2-year anniversary of the donation date	Each living donor organ recovered at the hospital This does not apply to covered VCA, domino donor, and non-domino therapeutic donor organs.

82

18.2 Timely Collection of Data

84

Table 18-2: Timely Data Collection

Information is timely if this Member:	Collects this information for this form:	Within this time period:
Transplant hospital	<i>Organ specific transplant recipient registration (TRR)</i>	When the transplant recipient is discharged from the hospital or 42 days following the transplant date, whichever is first

⁹⁶ This table has been truncated to show only the rows that have proposed changes to the policy language. Language not presented here will not be affected by this proposal.

Information is timely if this Member:	Collects this information for this form:	Within this time period:
Recovery hospital	<i>Living donor registration (LDR)</i>	When the living donor is discharged from the hospital or 42 days following the transplant date, whichever is first This does not apply to covered VCA transplants.
Recovery hospital	<i>Living donor follow-up (LDF)</i>	60 days before or after the six-month, 1-year, and 2-year anniversary of the donation date or This does not apply to covered VCA transplants.

85

86 18.3 Recording and Reporting the Outcomes of Organ Offers

87 The allocating OPO and the transplant hospitals that received organ offers share responsibility for
 88 reporting the outcomes of all organ offers. OPOs are responsible for reporting the outcomes of organ
 89 offers to the OPTN within 30 days of the match run date. OPOs, transplant hospitals, and the OPTN may
 90 report this information. The OPO or the OPTN must obtain PTR refusal codes directly from the physician,
 91 surgeon, or their designee involved with the potential recipient and not from other personnel.

92

93 If the OPO reports the refusal code, then the transplant hospital has 45 days from the match run date, to
 94 validate the refusal code by either confirming or amending the refusal code. If the OPO and transplant
 95 hospital report different refusal codes, then the OPTN will use the transplant hospital's refusal code for
 96 data analysis purposes.

97

98 If the OPTN reports the refusal code, then the transplant hospital will not be required to validate the
 99 refusal code.

100

101 This policy does not apply to ~~covered~~-VCA organ offers; ~~instead~~, members must document covered VCA
 102 offers according to *Policy 18.1: Data Submission Requirements*.

103

104

#

105

Bylaws Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary. The [...] signifies language in the current Policy that is not presented here for the purposes of brevity and will not be affected by the proposal.

106

107 **J.2 Primary VCA Transplant Surgeon Requirements**

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

110

- 111 1. The surgeon must have an M.D., D.O., or equivalent degree from another country, with a current
112 license to practice medicine in the hospital's state or jurisdiction.
- 113 2. The surgeon must be accepted onto the hospital's medical staff, and be on-site at this hospital.
- 114 3. The surgeon must have documentation from the hospital's credentialing committee that it has
115 verified the surgeon's state license, training, and continuing medical education, and that the
116 surgeon is currently a member in good standing of the hospital's medical staff.
- 117 4. ~~The surgeon must have observed at least 2 multi-organ procurements. These observations must be
118 documented in a log that includes the date of procurement and Donor ID.~~

119

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

121 In addition to the requirements as described in *Section J.2* above, the surgeon for an upper limb
122 transplant program must meet both/all of the following:

123

- 124 1. Have current certification by the American Board of Plastic Surgery, the American Board of
125 Orthopedic Surgery, the American Board of Surgery, or the Royal College of Physicians and
126 Surgeons of Canada. In the case of a surgeon who has just completed training and whose
127 board certification is pending, the Membership and Professional Standards Committee
128 (MPSC) may grant conditional approval for 24 months to allow time for the surgeon to
129 complete board certification, with the possibility of one additional 16-month extension.

130

131 In place of current certification by the American Board of Plastic Surgery, the American
132 Board of Orthopedic Surgery, the American Board of Surgery, the Royal College of Physicians
133 and Surgeons of Canada, or a pending certification, the surgeon must demonstrate the
134 following experience:

135

136

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141

- a. Acted as the first-assistant or primary surgeon on at least 1 covered VCA procurement.
- b. Participated in the pre-operative evaluation of at least 3 potential upper limb transplant patients.
- c. Acted as primary surgeon of at least 1 upper limb transplant.
- d. Participated in the post-operative follow-up of at least 1 upper limb recipient for 1 year post-transplant.

142 The upper limb procurement experience must be documented in a log that includes the
 143 Donor ID or other unique identifier that can be verified by the OPTN. The experience for
 144 upper limb transplant procedures must be documented in a log that includes the dates of
 145 procedures and evaluations, the role of the surgeon, and the medical record number or
 146 other unique identifier that can be verified by the OPTN. This log must be signed by the
 147 program director, division chief, or department chair where the experience was gained.
 148

149 In addition to experience above, a surgeon without current or pending certification by the
 150 American Board of Plastic Surgery, the American Board of Orthopedic Surgery, the American
 151 Board of Surgery, or the Royal College of Physicians and Surgeons of Canada must also:

- 152 a. Be ineligible for American board certification.
- 153 b. Provide a plan for continuing education that is comparable to American board
 154 maintenance of certification. This plan must at least require that the surgeon obtains 60
 155 hours of Category I continuing medical education (CME) credits with self-assessment
 156 that are relevant to the individual's practice every three years. Self-assessment is
 157 defined as a written or electronic question-and-answer exercise that assesses
 158 understanding of the material in the CME program. A score of 75% or higher must be
 159 obtained on self-assessments. Repeated attempts to achieve an acceptable self-
 160 assessment score are allowed. The transplant hospital must document completion of
 161 this continuing education.
- 162 c. Provide to the OPTN two letters of recommendation from directors of designated VCA
 163 transplant programs not employed by the applying hospital. These letters must address:
 - 164 i. Why an exception is reasonable.
 - 165 ii. The surgeon's overall qualifications to act as a primary upper limb transplant
 166 surgeon.
 - 167 iii. The surgeon's personal integrity, honesty, and familiarity with and experience in
 168 adhering to OPTN obligations and compliance protocols.
 - 169 iv. Any other matters judged appropriate.

170
 171 If the surgeon has not adhered to the plan for maintaining continuing education or has not
 172 obtained the necessary CME credits with self-assessment, the transplant program will have
 173 a six-month grace period to address these deficiencies. If the surgeon has not fulfilled the
 174 requirements after the six-month grace period, and a key personnel change application has
 175 not been submitted, then the transplant program will be referred to the MPSC for
 176 appropriate action according to *Appendix L* of these Bylaws. If the OPTN becomes aware
 177 that a primary surgeon has not been compliant for 12 months or more and deficiencies still
 178 exist, then the transplant program will not be given any grace period and will be referred to
 179 the MPSC for appropriate action according to *Appendix L* of these Bylaws.
 180

- 181 2. Completion of at least *one* of the following:
 - 182 a. Any Accreditation Council of Graduate Medical Education (ACGME) approved fellowship
 183 program in hand surgery.

- 184 b. A fellowship program in hand surgery that meets *all* of the following criteria:
- 185 i. The program is at a hospital that has inpatient facilities, operative suites and
- 186 diagnostic treatment facilities, outpatient facilities, and educational resources.
- 187 ii. The program is at an institution that has a proven commitment to graduate
- 188 medical education.
- 189 iii. The program director must have current certification in the sub-specialty by the
- 190 American Board of Orthopedic Surgery, the American Board of Plastic Surgery, or
- 191 American Board of Surgery.
- 192 iv. The program should have at least 2 physician faculty members with hand surgery
- 193 experience and current medical licensure who are actively involved in the
- 194 instruction and supervision of fellows during the time of accredited education.
- 195 v. The program is at a hospital that has affiliated rehabilitation medicine services.
- 196 vi. The program has the resources, including adequate clinical facilities, laboratory
- 197 research facilities, and appropriately trained faculty and staff, to provide research
- 198 experience.
- 199 c. At least 2 years of consecutive and independent practice of hand surgery and must have
- 200 completed a minimum number of upper limb procedures as the primary surgeon
- 201 according to *Table J-1* below. This includes completion of pre-operative assessments
- 202 and post-operative care for a minimum of 90 days after surgery. These procedures must
- 203 be documented in a log that includes the date of the procedure and the medical record
- 204 number or other unique identifier that can be verified by the OPTN. This log must be
- 205 signed by the program director, division chief, or department chair where the
- 206 experience was gained. Surgery of the hand includes only those procedures performed
- 207 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	10
Free flaps	
Non-surgical management	6
Replantation or Transplant	5

- 210
- 211 3. Observation of at least 2 multi-organ procurements. These observations must be documented
- 212 in a log that includes the date of procurement and Donor ID.

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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.2* above, the transplant surgeon for a head and neck transplant program must meet ~~both~~all of the following:

1. 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 Royal College of Physicians and Surgeons of Canada. 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 one additional 16-month extension.

In place of current certification by the American Board of Plastic Surgery, the American Board of Otolaryngology, the American Board of Oral and Maxillofacial Surgery, the American Board of Surgery, the Royal College of Physicians and Surgeons of Canada, or a pending certification, the surgeon must demonstrate the following experience:

- a. Acted as the first-assistant or primary surgeon on at least 1 covered VCA procurement.
- b. Participated in the pre-operative evaluation of at least 3 potential head and neck transplant patients.
- c. Acted as primary surgeon of at least 1 head and neck transplant.
- d. Participated in the post-operative follow-up of at least 1 head and neck recipient for 1 year post-transplant.

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

In addition to experience above, a surgeon without current or pending certification by the American Board of Plastic Surgery, the American Board of Otolaryngology, the American Board of Oral and Maxillofacial Surgery, the American Board of Surgery, or the Royal College of Physicians and Surgeons of Canada must also:

- a. Be ineligible for American board certification.
- b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the surgeon obtains 60

- 253 hours of Category I continuing medical education (CME) credits with self-assessment
 254 that are relevant to the individual's practice every three years. Self-assessment is
 255 defined as a written or electronic question-and-answer exercise that assesses
 256 understanding of the material in the CME program. A score of 75% or higher must be
 257 obtained on self-assessments. Repeated attempts to achieve an acceptable self-
 258 assessment score are allowed. The transplant hospital must document completion of
 259 this continuing education.
- 260 c. Provide to the OPTN two letters of recommendation from directors of designated VCA
 261 transplant programs not employed by the applying hospital. These letters must address:
- 262 i. Why an exception is reasonable.
 - 263 ii. The surgeon's overall qualifications to act as a primary head and neck transplant
 264 surgeon.
 - 265 iii. The surgeon's personal integrity, honesty, and familiarity with and experience in
 266 adhering to OPTN obligations and compliance protocols.
 - 267 iv. Any other matters judged appropriate.

268

269 If the surgeon has not adhered to the plan for maintaining continuing education or has not
 270 obtained the necessary CME credits with self-assessment, the transplant program will have
 271 a six-month grace period to address these deficiencies. If the surgeon has not fulfilled the
 272 requirements after the six-month grace period, and a key personnel change application has
 273 not been submitted, then the transplant program will be referred to the MPSC for
 274 appropriate action according to *Appendix L* of these Bylaws. If the OPTN becomes aware
 275 that a primary surgeon has not been compliant for 12 months or more and deficiencies still
 276 exist, then the transplant program will not be given any grace period and will be referred to
 277 the MPSC for appropriate action according to *Appendix L* of these Bylaws.

- 278
- 279 2. Completion of at least *one* of the following:
- 280 a. Any ACGME–approved fellowship program in otolaryngology, plastic, oral and
 281 maxillofacial, or craniofacial surgery.
 - 282 b. A fellowship program in otolaryngology, plastic, oral and maxillofacial, or craniofacial
 283 surgery that meets *all* of the following criteria:
 - 284 i. The program is at a hospital that has inpatient facilities, operative suites and
 285 diagnostic treatment facilities, outpatient facilities, and educational resources.
 - 286 ii. The program is at an institution that has a proven commitment to graduate
 287 medical education.
 - 288 iii. The program director must have current certification in the sub-specialty by the
 289 American Board of Plastic Surgery, the American Board of Otolaryngology, or
 290 the American Board of Oral and Maxillofacial Surgery.
 - 291 iv. The program should have at least two physician faculty members with head and
 292 neck surgery experience and current medical licensure who are actively involved
 293 in the instruction and supervision of fellows during the time of accredited
 294 education.

- 295 v. The program is at a hospital that has affiliated rehabilitation medicine services.
- 296 vi. The program has the resources, including adequate clinical facilities, laboratory
- 297 research facilities, and appropriately trained faculty and staff, to provide
- 298 research experience.
- 299
- 300 c. At least 2 years of consecutive and independent practice of head and neck surgery. The
- 301 surgeon must have completed at least 1 face transplant as primary surgeon or first-
- 302 assistant, or a minimum number of head and neck procedures as the primary surgeon
- 303 according to *Table J-2* below. This includes completion of pre-operative assessments
- 304 and post-operative care for a minimum of 90 days after surgery. These procedures must
- 305 be documented in a log that includes the dates of procedures and evaluations, the role
- 306 of the surgeon and the medical record number, Donor ID, or other unique identifier that
- 307 can be verified by the OPTN. This log must be signed by the program director, division
- 308 chief, or department chair where the experience was gained.
- 309
- 310

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

- 311
- 312 3. Observation of at least 2 multi-organ procurements. These observations must be documented
- 313 in a log that includes the date of procurement and Donor ID.
- 314

C. Additional Primary Surgeon Requirements for Abdominal Wall Transplant Programs

The primary surgeon for an abdominal wall transplant program must meet both of the following:

- 317 1. Meet the primary transplant surgeon requirements of a head and neck, intestine, kidney,
- 318 liver, pancreas, or upper limb transplant program.
- 319
- 320 2. Have observed at least 2 multi-organ procurements. These observations must be
- 321 documented in a log that includes the date of procurement and Donor ID.
- 322

D. Additional Primary Surgeon Requirements for Uterus Transplant Programs

In addition to the requirements as described in Section J.2 above, the primary surgeon for a uterus transplant program must meet all of the following:

- 327
- 328 1. Have current certification by the American Board of Surgery, the American Board of
- 329 Obstetrics and Gynecology, the American Osteopathic Board of Obstetrics and Gynecology,
- 330 the American Board of Urology, the American Board of Osteopathic Surgery, or the Royal
- 331 College of Physicians and Surgeons of Canada. In the case of a surgeon who has just

332 completed training and whose board certification is pending, the Membership and
 333 Professional Standards Committee (MPSC) may grant conditional approval for 24 months to
 334 allow time for the surgeon to complete board certification, with the possibility of one
 335 additional 16-month extension.

336 In place of current certification by the American Board of Surgery, the American Board of
 337 Obstetrics and Gynecology, the American Osteopathic Board of Obstetrics and Gynecology,
 338 the American Board of Urology, the American Board of Osteopathic Surgery, or the Royal
 339 College of Physicians and Surgeons of Canada, or a pending certification, the surgeon must:

- 340 a. Be ineligible for American board certification.
- 341 b. Provide a plan for continuing education that is comparable to American board
 342 maintenance of certification. This plan must at least require that the surgeon obtains 60
 343 hours of Category I continuing medical education (CME) credits with self-assessment
 344 that are relevant to the individual's practice every three years. Self-assessment is
 345 defined as a written or electronic question-and-answer exercise that assesses
 346 understanding of the material in the CME program. A score of 75% or higher must be
 347 obtained on self-assessments. Repeated attempts to achieve an acceptable self-
 348 assessment score are allowed. The transplant hospital must document completion of
 349 this continuing education.
- 350 c. Provide to the OPTN two letters of recommendation from directors of designated VCA,
 351 kidney, liver, intestine, or pancreas transplant programs not employed by the applying
 352 hospital. These letters must address:
- 353 i. Why an exception is reasonable.
- 354 ii. The surgeon's overall qualifications to act as a primary uterus transplant surgeon.
- 355 iii. The surgeon's personal integrity, honesty, and familiarity with and experience in
 356 adhering to OPTN obligations and compliance protocols.
- 357 iv. Any other matters judged appropriate.

358

359 If the surgeon has not adhered to the plan for maintaining continuing education or has not
 360 obtained the necessary CME credits with self-assessment, the transplant program will have
 361 a six-month grace period to address these deficiencies. If the surgeon has not fulfilled the
 362 requirements after the six-month grace period, and a key personnel change application has
 363 not been submitted, then the transplant program will be referred to the MPSC for
 364 appropriate action according to Appendix L of these Bylaws. If the OPTN becomes aware
 365 that a primary surgeon has not been compliant for 12 months or more and deficiencies still
 366 exist, then the transplant program will not be given any grace period and will be referred to
 367 the MPSC for appropriate action according to Appendix L of these Bylaws.

- 368 2. Have experience in organ procurement by meeting either of the following:
- 369 a. Observation or completion of at least 2 multi-organ procurements within the last five
 370 years. These observations or procurements must be documented in a log that
 371 includes the date of procurement and Donor ID.

- 372 b. Completion of one deceased donor uterus procurement as primary surgeon within
373 the last five years. This experience must be documented in a log that includes the
374 date of procurement and Donor ID.
375
- 376 3. Completion of at least one of the following:
- 377 a. Any ACGME-approved fellowship program in gynecologic oncology.
378 b. A fellowship program in gynecologic oncology that meets all of the following
379 criteria:
- 380 i. The fellowship program is at a hospital that has inpatient facilities, operative
381 suites and diagnostic treatment facilities, outpatient facilities, and
382 educational resources.
- 383 ii. The fellowship program is at an institution that has a proven commitment to
384 graduate medical education.
- 385 iii. The fellowship program director must have current certification in the sub-
386 specialty by the American Board of Surgery, the American Board of
387 Obstetrics and Gynecology, or the American Osteopathic Board of
388 Obstetrics and Gynecology.
- 389 iv. The fellowship program should have at least 2 physician faculty members
390 with gynecologic surgery experience and current medical licensure who are
391 actively involved in the instruction and supervision of fellows during the
392 time of accredited education.
- 393 v. The fellowship program has the resources, including adequate clinical
394 facilities, laboratory research facilities, and appropriately trained faculty and
395 staff, to provide research experience.
- 396 c. Either a formal 2-year surgical transplant fellowship or clinical experience meeting
397 the requirements for the primary transplant surgeon of a kidney, liver, intestine, or
398 pancreas transplant program as outlined in Appendices E, F, or G.
- 399 d. Completion of at least 2 uterus transplants within the last five years as the primary
400 surgeon or co-surgeon. This includes completion of pre-operative assessments and
401 post-operative care for a minimum of 90 days after surgery. These transplants must
402 be documented in a log that includes the date of the transplant, the role of the
403 surgeon in the transplant, and the medical record number or other unique identifier
404 that can be verified by the OPTN. This log must be signed by the program director,
405 division chief, or department chair where the experience was gained.
- 406 e. Completion of at least 15 radical hysterectomies within the last five years as the
407 primary surgeon. These procedures must be documented in a log that includes the
408 date of the procedure, the type of procedure, the role of the surgeon in the
409 procedure, and the medical record number or other unique identifier that can be
410 verified by the OPTN. This log must be signed by the program director, division
411 chief, or department chair where the experience was gained.
412
- 413 4. Show proof of collaboration with experts in these fields:

- 414 • Abdominal organ (kidney, liver, intestine, or pancreas) transplant surgery
- 415 • Gynecologic oncology
- 416 • Maternal fetal medicine
- 417 • Neonatology
- 418 • Reproductive endocrinology/infertility
- 419 • Urology
- 420 • Uterus transplant surgery

421 The primary surgeon, the primary physician, and the primary obstetrician-gynecologist for the
 422 uterus transplant program may fulfill some of these requirements if they are experts in these
 423 fields.

425 **D-E. Additional Primary Surgeon Requirements for Other VCA Transplant Programs**

426 This pathway is only for the primary transplant surgeon at a VCA transplant program intending
 427 to transplant covered VCA body parts other than those that will be transplanted at approved
 428 upper limb, head and neck, ~~or~~ abdominal wall, or uterus transplant programs. The VCA
 429 transplant program must specify the types of body parts it will transplant in the application from
 430 the following options: external male genitalia, other genitourinary organ, vascularized gland,
 431 lower limb, musculoskeletal composite graft segment, or spleen. In addition to the requirements
 432 as described in section J.2 above, the primary surgeon for other VCA transplant programs must
 433 meet *all* of the following:

434
 435 1. Have current American Board of Medical Specialties or Royal College of Physicians
 436 and Surgeons of Canada certification in a specialty relevant to the type of VCA
 437 transplant the surgeon will be performing.

438
 439 In place of current certification by the American Board of Medical Specialties or the
 440 Royal College of Physicians and Surgeons of Canada, the surgeon must:

- 441 a. Be ineligible for American board certification.
- 442 b. Provide a plan for continuing education that is comparable to American board
 443 maintenance of certification. This plan must at least require that the surgeon
 444 obtains 60 hours of Category I continuing medical education (CME) credits with
 445 self-assessment that are relevant to the individual's practice every three years.
 446 Self-assessment is defined as a written or electronic question-and-answer
 447 exercise that assesses understanding of the material in the CME program. A
 448 score of 75% or higher must be obtained on self-assessments. Repeated
 449 attempts to achieve an acceptable self-assessment score are allowed. The
 450 transplant hospital must document completion of this continuing education.
- 451 c. Provide to the OPTN two letters of recommendation from directors of
 452 designated VCA transplant programs not employed by the applying hospital.
 453 These letters must address:
 - 454 i. Why an exception is reasonable.

- 455 ii. The surgeon’s overall qualifications to act as a primary VCA transplant
456 surgeon.
457 iii. The surgeon’s personal integrity, honesty, and familiarity with and
458 experience in adhering to OPTN obligations and compliance protocols.
459 iv. Any other matters judged appropriate.

460
461 If the surgeon has not adhered to the plan for maintaining continuing education
462 or has not obtained the necessary CME credits with self-assessment, the
463 transplant program will have a six-month grace period to address these
464 deficiencies. If the surgeon has not fulfilled the requirements after the six-
465 month grace period, and a key personnel change application has not been
466 submitted, then the transplant program will be referred to the MPSC for
467 appropriate action according to *Appendix L* of these Bylaws. If the OPTN
468 becomes aware that a primary surgeon has not been compliant for 12 months
469 or more and deficiencies still exist, then the transplant program will not be
470 given any grace period and will be referred to the MPSC for appropriate action
471 according to *Appendix L* of these Bylaws.

- 472
473 2. Have observed at least 2 multi-organ procurements. These observations must be
474 documented in a log that includes the date of procurement and Donor ID.
475 ~~2.~~ 3. Have performed the pre-operative evaluation of at least 3 potential VCA
476 transplant patients.
477 ~~3.~~ 4. Have current working knowledge in the surgical specialty, defined as independent
478 practice in the specialty over a consecutive five-year period.
479 ~~4.~~ 5. Have assembled a multidisciplinary surgical team that includes specialists necessary
480 to complete the VCA transplant including, for example, plastic surgery, orthopedics,
481 otolaryngology, obstetrics and gynecology, urology, or general surgery. The team must
482 have demonstrated detailed planning that is specific for the type of VCA transplant the
483 program will perform.

484
485 This team must include a team member that has microvascular experience such as
486 replantation, revascularization, free tissue transfer, and major flap surgery. At least two
487 of these These procedures must be documented in a log that includes the dates of
488 procedures, the role of the surgeon, and the medical record number, or other unique
489 identifier that can be verified by the OPTN. This log must be signed by the program
490 director, division chief, or department chair where the experience was gained. ~~The team~~
491 ~~must have demonstrated detailed planning that is specific for the types of VCA~~
492 ~~transplant the program will perform.~~

493
494 A letter from the presiding executive of the transplant hospital where the VCA
495 transplant will be performed must provide written verification that requirements 1
496 through 45 above have been met by the primary surgeon.

497 [...]

498

499 **J.4 Primary Obstetrician-Gynecologist Requirement for Uterus Transplant Programs**

500

501 Each designated uterus transplant program must have a primary obstetrician-gynecologist who meets all
502 of the following requirements:

- 503 1. Has an M.D., D.O., or equivalent degree from another country, with a current license to practice
504 medicine in the hospital’s state or jurisdiction.
- 505 2. Is accepted onto the hospital’s medical staff, and is on-site at this hospital.
- 506 3. Has documentation from the hospital’s credentialing committee that it has verified the obstetrician-
507 gynecologist’s state license, board certification, training, and continuing medical education, and that
508 the obstetrician-gynecologist is currently a member in good standing of the hospital’s medical staff.
- 509 4. Has current board certification in obstetrics and gynecology by the American Board of Obstetrics
510 and Gynecology, the American Osteopathic Board of Obstetrics and Gynecology, or the Royal
511 College of Physicians and Surgeons of Canada.

512

513 In place of current certification in obstetrics and gynecology by the American Board of Obstetrics
514 and Gynecology, the American Osteopathic Board of Obstetrics and Gynecology, or the Royal
515 College of Physicians and Surgeons of Canada, the obstetrician-gynecologist must:

- 516 • Be ineligible for American board certification.
- 517 • Provide a plan for continuing education that is comparable to American board maintenance
518 of certification. This plan must at least require that the obstetrician-gynecologist obtains 60
519 hours of Category I continuing medical education (CME) credits with self-assessment that
520 are relevant to the individual’s practice every three years. Self-assessment is defined as a
521 written or electronic question-and-answer exercise that assesses understanding of the
522 material in the CME program. A score of 75% or higher must be obtained on self-
523 assessments. Repeated attempts to achieve an acceptable self-assessment score are
524 allowed. The transplant hospital must document completion of this continuing education.
- 525 • Provide to the OPTN two letters of recommendation from directors of obstetrics and
526 gynecology departments not employed by the applying hospital. These letters must address:
- 527 i. Why an exception is reasonable.
- 528 ii. The obstetrician-gynecologist’s overall qualifications to act as a primary
529 obstetrician-gynecologist.
- 530 iii. The obstetrician-gynecologist’s personal integrity and honesty.
- 531 iv. Any other matters judged appropriate.

532

533 **J.5 Uterus Transplant Programs That Perform Living Donor Recovery**

534 A uterus recovery hospital is a designated uterus transplant program that performs the surgery to
535 recover uteri for transplantation from living donors. Uterus recovery hospitals must meet all the
536 requirements of a designated uterus transplant program as outlined above and must also have protocols
537 and resources in place for performing living donor assessments.

538

539

A. Living Donor Medical Evaluation

540

The uterus recovery hospital must have the clinical resources available to assess the medical condition of and specific risks to the living donor.

542

543

B. Living Donor Psychosocial Evaluation

544

The uterus recovery hospital must have the clinical resources to perform a psychosocial evaluation of the living donor.

546

547

C. Independent Living Donor Advocate (ILDA)

548

The uterus recovery hospital must have an independent living donor advocate (ILDA) who is not involved with the evaluation or treatment decisions of the potential recipient, and is a knowledgeable advocate for the living donor. The ILDA must be independent of the decision to transplant the potential recipient and follow the protocols that outline the duties and responsibilities of the ILDA according to OPTN *Policy 14.2: Independent Living Donor Advocate (ILDA) Requirements*.

554

555

D. Living Donor Uterus Surgeon Requirements

556

A uterus recovery hospital must have on-site at least one uterus recovery surgeon who has demonstrated experience as the primary surgeon, co-surgeon, or first assistant, within the last five years, of at least 10 radical hysterectomies, living donor uterus recoveries, or some combination thereof.

560

561

The demonstrated experience of the uterus recovery surgeon must include one of the following, performed as the primary surgeon or co-surgeon, within the last five years:

563

- At least 2 living donor uterus recoveries or
- 1 living donor uterus recovery, at least 1 deceased donor uterus procurement, and at least 1 direct observation of living donor uterus recovery, or
- At least 2 deceased donor uterus procurements and at least 2 direct observations of living donor uterus recoveries.

564

565

566

567

568

These procedures must be documented in a log that includes the date of the procedure, the type of procedure, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN. This log must be signed by the program director, division chief, or department chair where the experience was gained.

572

573

Appendix N: Definitions

574

C

575

Covered Vascularized Composite Allograft body parts (covered VCAs)

576

The body parts listed below are covered VCAs. Covered VCAs are categorized by type as follows:

Covered VCA(s)	Type:
Any group of vascularized body parts from the upper limb	Upper limb
Face, larynx, vascularized parathyroid gland, scalp, trachea, vascularized thyroid, and any other vascularized body parts from the head and neck	Head and neck
Abdominal wall, symphysis pubis, and any group of vascularized skeletal elements of the pelvis	Abdominal wall
Uterus, internal and external male and female genitalia, and urinary bladder	Genitourinary organ
<u>Uterus, cervix, and vagina</u>	<u>Uterus</u>
<u>Penis and scrotum</u>	<u>External male genitalia</u>
<u>Internal male genitalia; external and internal female genitalia other than uterus, cervix, and vagina; and urinary bladder</u>	<u>Other genitourinary organ</u>
Adrenal and thymus	Vascularized gland
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	Lower limb
Spine axis, chest wall, and other composite graft of vascularized muscle, bone, nerve, or skin	Musculoskeletal composite graft segment
Spleen	Spleen

577 **D**

578 **Designated Transplant Program**

579 An organ-specific program that has been approved by the OPTN as part of the transplant hospital
 580 membership. A transplant hospital member may have transplant programs for transplantation of hearts,
 581 lungs, liver, kidneys, pancreas, pancreas islets, intestines, upper limbs, head and neck VCAs,
 582 abdominal walls, uteri, external male genitalia, other genitourinary organs, vascularized glands,
 583 lower limbs, musculoskeletal composite graft segments, and spleens. In order to be a transplant
 584 hospital member, the transplant hospital must have current designated transplant program approval for

585 at least one organ. A designated transplant program may also be called a transplant program in these
586 Bylaws.

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