OPTN

Public Comment Proposal

Establish Membership Requirements for Uterus Transplant Programs

OPTN Vascularized Composite Allograft Transplantation Committee

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Contents

Establish Membership Requirements for Uterus Transplant Programs

Affected Policy:	*Policy 1.2 Definitions*
Affected Bylaws:	*Appendix J: Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs* *Appendix N: Definitions*
Sponsoring Committee:	*Vascularized Composite Allograft Transplantation*
Public Comment Period:	*August 3, 2021 – September 30, 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 (20 out of the 32) were made possible through living donation, but the OPTN has not yet established requirements for transplant programs performing living donor uterus recoveries. 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.

Background

Vascularized composite allografts (VCA) were designated as organs under the purview of the OPTN effective July 3, 2014.[1,2] 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.[3] 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.[4] 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.[5] 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

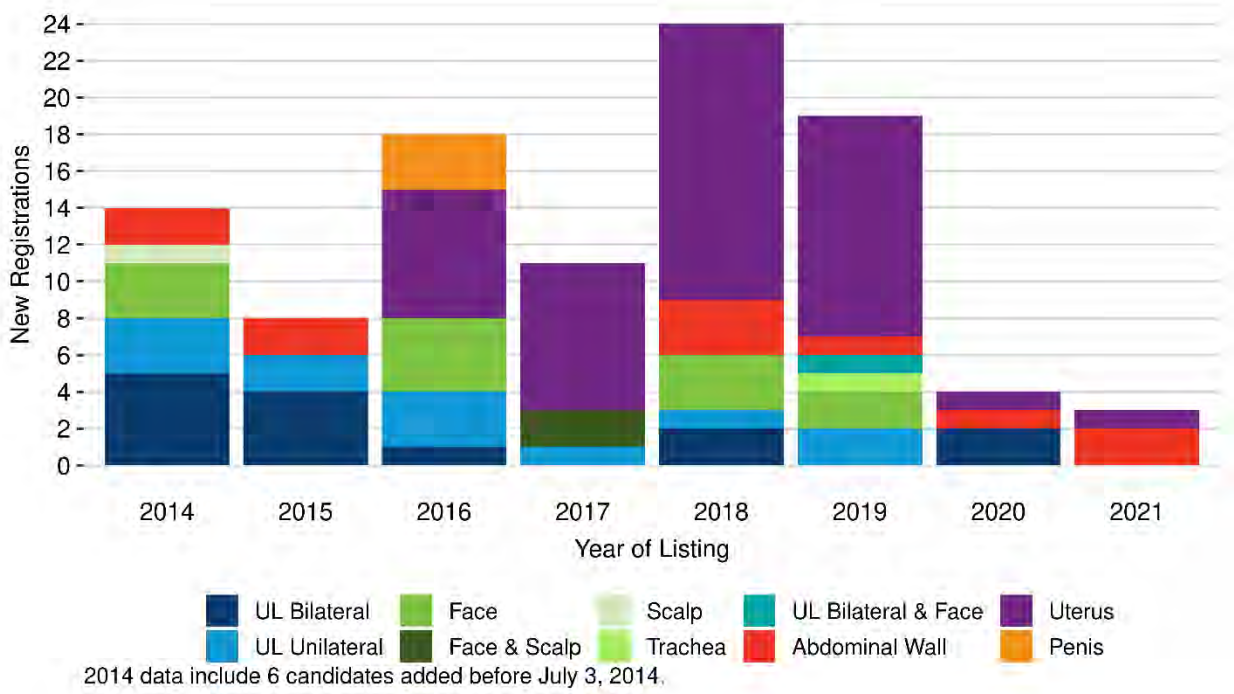
Type of VCA	Covered VCA Body Parts	Membership Requirements
Upper limb	Any group of vascularized body parts from the upper limb	Upper limb
Head and neck	Face, larynx, vascularized parathyroid gland, scalp, trachea, vascularized thyroid, and any other vascularized body parts from the head and neck	Head 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 genitourinary organ VCA type includes uterus and penis, as well as urinary bladder and other internal and external male and female genitalia. Currently, there are nine transplant programs approved

[1] 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.
[2] "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.
[3] "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.
[4] "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.
[5] "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.

by the OPTN to perform genitourinary organ transplants.[6] Two of these programs have each performed a successful penis transplant through deceased donation, one for a cancer survivor and one for a wounded veteran.[7,8] Three of these programs have performed at least 32 uterus transplants since 2016 for patients with absolute uterine factor infertility.[9] These transplants have resulted in at least 21 live births, and most of these transplants (20 of 32, or 63%) were made possible through living uterus donation.[10] Another approved program recently opened for referrals for uterus transplantation, and four additional hospitals in the U.S. are building uterus transplant programs.[11] While uterus transplantation has shown promising success to date, eight of the 32 transplanted uterus grafts failed.[12] 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 – May 31, 2021[13]



[6] "Member Directory," OPTN, accessed June 14, 2021, https://optn.transplant.hrsa.gov/members/member-directory/.
[7] 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.
[8] 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.
[9] OPTN data as of June 11, 2021.
[10] OPTN data as of June 24, 2021.
[11] 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.
[12] Ibid.
[13] OPTN data as of May 31, 2021.

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.[14] 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."[15] 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).[16,17] IUGR can result in stillbirth, preterm delivery and associated risks, and adverse health effects throughout childhood and adulthood.[18,19]

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.[20] 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.[21]

[14] Liza Johannesson, Anji Wall, Andreas Tzakis, et al. "Life underneath the VCA umbrella: perspectives from the United States Uterus Transplantation Consortium."
[15] "OPTN Bylaws," OPTN, accessed June 15, 2021, https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf.
[16] 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.
[17] 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
[18] Suhag and Berghella, "Intrauterine Growth Restriction," 103.
[19] 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.
[20] "Strategic Plan 2021-2024," OPTN, accessed June 24, 2021, https://optn.transplant.hrsa.gov/media/4632/optn-strategic-plan-2021-2024.pdf.
[21] "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.

Overview of Proposal

The Committee proposes updating OPTN Policies 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."[22] 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,[23] whereas the surgeons who led the teams that have performed

[22] "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.
[23] 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.[24,25] No other types of genitourinary organ transplantation have been performed in the U.S. since 2014.[26] 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 32 transplants performed as of May 2021.[27] Additionally, the volume of uterus transplants performed is expected to grow, given significant interest from both potential recipients and potential living donors.[28] 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.[29]

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 May 2021.[30] 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.[31]

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 of testicular transplant[32,33] and ovarian transplant[34] have been documented in the U.S., these cases pre-

[24] "Penis Transplant Program," Johns Hopkins Medicine, accessed June 25, 2021, https://www.hopkinsmedicine.org/dev/xtest_kara/reconstructive-transplant/penis-transplant.html#ourteam.
[25] 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/.
[26] OPTN data as of May 31, 2021.
[27] Ibid.
[28] Living Donor Committee Meeting Summary, May 12, 2021, OPTN, accessed June 24, 2021, https://optn.transplant.hrsa.gov/media/4656/20210512_ldc_summary.pdf.
[29] BP Jones, NJ Williams, S Saso, et al., "Uterine transplantation in transgender women," *BJOG* 126 (2019): 152-156, doi:10.1111/1471-0528.15438.
[30] Based on OPTN data as of May 31, 2021.
[31] 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.
[32] Sherman J. Silber, "Transplantation of a human testis for anorcha," *Fertility and Sterility* 30, no. 2 (August 1978): 181-187, https://www.fertstert.org/article/S0015-0282(16)43457-6/pdf.
[33] 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.
[34] Sherman J. Silber, Gedis Grudzinskas, and Roger G. Gosden, "Successful Pregnancy after Microsurgical Transplantation of an

date 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:[35]

- 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
- 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

Intact Ovary," *New England Journal of Medicine* 359 (2008): 2617-2618, https://www.nejm.org/doi/full/10.1056/NEJMc0804321.

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

and Donor ID.[36] 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.[37] 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.[38] 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,[39] and the ACGME recognizes certification from either ABOG or AOBOG as appropriate qualifications for program directors and faculty members of graduate medical education programs in obstetrics and gynecology.[40]

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).

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[36] Ibid.

[37] "Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs," OPTN, Briefing Paper, June 2015.

[38] Suganuma et al., "Uterus transplantation," 308.

[39] "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/.

[40] "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/PFAssets/ProgramRequirements/220_ObstetricsAndGynecology_2020.pdf?ver=2020-06-29-162338-630.

The alternative requirements are consistent with those available to the primary surgeons of abdominal organ and thoracic organ transplant programs:[41]

- 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.[42]

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.[43,44] Gynecologic oncology is the subspecialty of obstetrics and gynecology that is most applicable to uterus transplantation because it entails significant surgical experience with relevant procedures, particularly hysterectomies.[45] Since accreditation of obstetrics and gynecology fellowship programs has transitioned to ACGME from the ABOG relatively recently,[46,47] 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.

[41] OPTN Bylaws, OPTN, available at https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf.
[42] "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.
[43] 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.
[44] "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/.
[45] "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.
[46] "For Residents," American Board of Obstetrics and Gynecology, accessed May 28, 2021, https://www.abog.org/program-resources/for-residents.
[47] "Subspecialty Procedural Volume Guidelines," ACGME Review Committee for Obstetrics and Gynecology.

- 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.[48]

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.[49] 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 procedure to uterus graft retrieval.[50] 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).[51]

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.

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[48] OPTN Bylaws, OPTN, available at https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf.
[49] 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.
[50] 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.
[51] "Surgery for Cervical Cancer," American Cancer Society, accessed May 25, 2021, https://www.cancer.org/cancer/cervical-cancer/treating/surgery.html.

Between 2016 and May 2021, 32 uterus transplants were performed in the U.S. across three transplant centers,[52] and at least 65 uterus transplants have been performed worldwide since 2000.[53] 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.[54] 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.[55] 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.[56]

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.[57] 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

[52] OPTN data as of June 11, 2021

[53] 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.

[54] 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.

[55] "Subspecialty Procedural Volume Guidelines," ACGME Review Committee for Obstetrics and Gynecology.

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

[57] 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.

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.[58] 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 programs[59] 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.[60] 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.[61,62] These existing requirements combined with the requirements proposed by the Committee largely align with the composition of the uterus transplantation team as recommended by the American Society for Reproductive Medicine in 2018.[63]

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

[58] Malasevskaia and Al-Awadhi, "A New Approach for Treatment of Women With Absolute Uterine Factor Infertility," e12772.
[59] Unless otherwise designated as a transplant program under 42 C.F.R. §121.9(a)(1) or (a)(3).
[60] 42 C.F.R. §121.9(a)(2)
[61] 42 CFR §121.9 (a)(2)(vii)
[62] OPTN Bylaws *Section D.9.E Mental Health and Social Support,* OPTN, available at https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf.
[63] Practice Committee of the American Society of Reproductive Medicine, "American Society for Reproductive Medicine position statement on uterus transplantation," 606.

anastomoses.[64,65,66,67] 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,[68] whereas surgeons with more in-depth microvascular experience tend to be trained in plastic surgery.[69] 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.[70] 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:
    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* though *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,

[64] 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.
[65] 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.
[66] Giuliano Testa and Liza Johannesson, "The Value of a Nulliparous Uterus," *Transplantation* 105, no. 5 (May 2021): 958-959, DOI: 10.1097/TP.0000000000003347.
[67] 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.
[68] Suganuma et al., "Uterus transplantation," 308.
[69] 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.
[70] OPTN Bylaws, OPTN, available at https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf.

including immunosuppression,[71] 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.[72]

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.[73] 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 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.[74] 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

[71] "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.
[72] "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.
[73] Malasevskaia and Al-Awadhi, "A New Approach for Treatment of Women With Absolute Uterine Factor Infertility," e12772.
[74] 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.

- 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.[75]

Living Donor Recovery Requirements

OPTN Bylaws include additional requirements for transplant programs that perform living donor recovery of livers and kidneys. Since 20 living donor uterus transplants have been performed in the U.S. to date[76] 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
- 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 approved by the OPTN Board of Directors to update *Policy 14* to include all living donors, including living uterus donors.[77]

The Committee also proposes requirements for the living donor uterus surgeon, similar to current requirements for the living donor liver surgeon.[78] 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. At least 2 of these 10 procedures must be living donor uterus recoveries performed as primary surgeon or co-surgeon. All procedures must be documented in a detailed log. These requirements will ensure that the living donor

[75] 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.
[76] OPTN data as of May 31, 2021.
[77] "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/.
[78] OPTN Bylaws, OPTN, available at https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf.

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.[79]

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 Bylaws[80] requires the primary surgeon to have assembled a multidisciplinary team that includes specialists necessary to complete the VCA transplant. This section 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.

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.[81] 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.[82]

NOTA and Final Rule Analysis

The Committee submits this proposal under the authority of the National Organ Transplant Act, which requires the OPTN to "establish membership criteria,"[83] 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.[84] Furthermore, the OPTN Final Rule requires designated transplant programs[85] to have "adequate

[79] 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.
[80] OPTN Bylaws, OPTN, available at https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf.
[81] "Principles for Data Collection," OPTN, accessed April 2, 2021, https://optn.transplant.hrsa.gov/members/committees/data-advisory-committee/.
[82] 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.
[83] 42 USC §274 (b)(2)(B)
[84] 42 CFR §121.4 (a)(4)
[85] Unless otherwise designated as a transplant program under 42 C.F.R. §121.9(a)(1) or (a)(3).

resources to provide transplant services to its patients."[86] 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."[87] The OPTN meets this requirement by listing the body parts covered by VCA-specific policies and bylaws in OPTN *Policy 1.2: Definitions*.[88] 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. Further, this proposal specifically provides that the reference to "uterus" in this policy will refer to the uterus, cervix, and vagina, which aligns with the OPTN Final Rule requirement that a VCA must contain multiple tissue types.[89]

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.[90] 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 on the UNOS website. 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

[86] 42 CFR §121.9(a)(2)
[87] 42 CFR §121.4(e)(3)
[88] "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/.
[89] 42 CFR §121.2.
[90] 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)."

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.

Projected Impact on the OPTN

Policy and Community Relations (PCR) hosted a workgroup to develop proposed membership requirements for uterus transplant programs and worked closely with Member Quality to ensure the proposed requirements are consistent with current OPTN Bylaws and the goals of the MPSC.

A Small IT Implementation effort, estimated at 300 hours, involves submitting data collection changes to OMB; updating membership systems with the new VCA membership application; and updating OPTN computer systems to reflect changes to designated VCA transplant programs and membership approvals. Member Quality anticipates 200 implementation hours to develop membership application changes and to assist members in submission and review of the applications.

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 would be formally evaluated approximately 1-year post-implementation. The following metrics, and any others subsequently requested by the Committee, would 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

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.

The Committee seeks feedback on the following questions:

- Do the proposed changes to the list of covered body parts that are considered VCAs under the OPTN Final Rule definition[91] appropriately represent the types of genitourinary organs that might be transplanted together under current clinical practice?
    - Uterus: Includes uterus, cervix, and vagina
    - External male genitalia: Includes penis and scrotum
    - Other genitourinary organ: Includes internal male genitalia; external and internal female genitalia other than uterus, cervix, and vagina; and urinary bladder
- Do the proposed membership requirements for uterus transplant programs provide adequate flexibility to account for variation in the uterus transplant field in how hospitals develop multidisciplinary teams?
- Will the proposed membership requirements ensure that approved uterus transplant programs have the expertise needed to safely perform uterus transplants, and, as applicable, living donor uterus recovery?
- Are there any requirements that should be removed or relaxed, or any additional requirements that should be included?
- Do members understand which procedures qualify as "radical hysterectomies"?

[91] 42 CFR §121.2.

Policy and 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.

OPTN Policies

1.2 Definitions

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

C

Covered Vascularized Composite Allograft body parts (covered VCAs)

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~~
Uterus, cervix, and vagina	Uterus
Penis and scrotum	External male genitalia
Internal male genitalia; external and internal female genitalia other than uterus, cervix, and vagina; and urinary bladder	Other genitourinary organ
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

OPTN Bylaws

J.2 Primary VCA Transplant Surgeon Requirements

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

1. 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.
2. The surgeon must be accepted onto the hospital's medical staff, and be on-site at this hospital.
3. 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.
4. ~~The surgeon must have observed at least 2 multi-organ procurements. These observations must be documented in a log that includes the date of procurement and Donor ID.~~

A. Additional Primary Surgeon Requirements for Upper Limb Transplant Programs

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

1. Have current certification by the American Board of Plastic Surgery, the American Board of Orthopedic 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 Orthopedic 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 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.

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

In addition to experience above, a surgeon without current or pending certification by the American Board of Plastic Surgery, the American Board of Orthopedic 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 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
c. Provide to the OPTN Contractor two letters of recommendation from directors of designated VCA transplant programs not employed by the applying hospital. These letters must address:
    i. Why an exception is reasonable.
    ii. The surgeon's overall qualifications to act as a primary upper limb transplant surgeon.
    iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
    iv. Any other matters judged appropriate.

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

deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws.

2. Completion of at least *one* of the following:
   a. Any Accreditation Council of Graduate Medical Education (ACGME) approved fellowship program in hand surgery.
   b. A fellowship program in hand surgery that meets *all* of the following criteria:
      i. The program is at a hospital that has inpatient facilities, operative suites and diagnostic treatment facilities, outpatient facilities, and educational resources.
      ii. The program is at an institution that has a proven commitment to graduate medical education.
      iii. The program director must have current certification in the sub-specialty by the American Board of Orthopedic Surgery, the American Board of Plastic Surgery, or American Board of Surgery.
      iv. The program should have at least 2 physician faculty members with hand surgery experience and current medical licensure who are actively involved in the instruction and supervision of fellows during the time of accredited education.
      v. The program is at a hospital that has affiliated rehabilitation medicine services.
      vi. The program has the resources, including adequate clinical facilities, laboratory research facilities, and appropriately trained faculty and staff, to provide research experience.
   c. At least 2 years of consecutive and independent practice of hand surgery and must have completed a minimum number of upper limb procedures as the primary surgeon according to *Table J-1* below. This includes completion of pre-operative assessments and post-operative care for a minimum of 90 days after surgery. These procedures must be documented in a log that includes the date of the procedure and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained. Surgery of the hand includes only those procedures performed on the upper limb below the elbow.

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

Type of Procedure	Minimum Number of Procedures
Bone	20
Nerve	20
Tendon	20
Skin or Wound Problems	14
Contracture or Joint Stiffness	10
Tumor	10
Microsurgical Procedures Free flaps	10

Type of Procedure	Minimum Number of Procedures
Non-surgical management	6
Replantation or Transplant	5

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

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

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

2. Completion of at least *one* of the following:
    a. Any ACGME–approved fellowship program in otolaryngology, plastic, oral and maxillofacial, or craniofacial surgery.
    b. A fellowship program in otolaryngology, plastic, oral and maxillofacial, or craniofacial surgery that meets *all* of the following criteria:
        i. The program is at a hospital that has inpatient facilities, operative suites and diagnostic treatment facilities, outpatient facilities, and educational resources.

ii. The program is at an institution that has a proven commitment to graduate medical education.
iii. The program director must have current certification in the sub-specialty by the American Board of Plastic Surgery, the American Board of Otolaryngology, or the American Board of Oral and Maxillofacial Surgery.
iv. The program should have at least two physician faculty members with head and neck surgery experience and current medical licensure who are actively involved in the instruction and supervision of fellows during the time of accredited education.
v. The program is at a hospital that has affiliated rehabilitation medicine services.
vi. The program has the resources, including adequate clinical facilities, laboratory research facilities, and appropriately trained faculty and staff, to provide research experience.

c. At least 2 years of consecutive and independent practice of head and neck surgery. The surgeon must have completed at least 1 face transplant as primary surgeon or first-assistant, or a minimum number of head and neck procedures as the primary surgeon according to *Table J-2* below. This includes completion of pre-operative assessments and post-operative care for a minimum of 90 days after surgery. These procedures must be documented in a log that includes the dates of procedures and evaluations, the role of the surgeon and the medical record number, Donor ID, or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained.

Table J-2: Minimum Procedures for Head and Neck Primary Transplant Surgeons

Type of Procedure	Minimum Number of Procedures
Facial trauma with bone fixation	10
Head or neck free tissue reconstruction	10

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

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:

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

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:

1. Have current certification by the American Board of Surgery, the American Board of Obstetrics and Gynecology, the American Osteopathic Board of Obstetrics and Gynecology, the American Board of Urology, the American Board of Osteopathic 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 Surgery, the American Board of Obstetrics and Gynecology, the American Osteopathic Board of Obstetrics and Gynecology, the American Board of Urology, the American Board of Osteopathic Surgery, or the Royal College of Physicians and Surgeons of Canada, or a pending certification, the surgeon must:
   d. Be ineligible for American board certification.
   e. 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 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
   f. Provide to the OPTN two letters of recommendation from directors of designated VCA, kidney, liver, intestine, or pancreas transplant programs not employed by the applying hospital. These letters must address:
      v. Why an exception is reasonable.
      vi. The surgeon's overall qualifications to act as a primary uterus transplant surgeon.
      vii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
      viii. Any other matters judged appropriate.

   If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six-month grace period, and a key personnel change application has

not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws. If the OPTN becomes aware that a primary surgeon has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws.

3. Have experience in organ procurement by meeting *either* of the following:
    a. Observation or completion of at least 2 multi-organ procurements within the last five years. These observations or procurements must be documented in a log that includes the date of procurement and Donor ID.
    b. Completion of one deceased donor uterus procurement as primary surgeon within the last five years. This experience must be documented in a log that includes the date of procurement and Donor ID.

4. Completion of at least *one* of the following:
    a. Any ACGME-approved fellowship program in gynecologic oncology.
    b. A fellowship program in gynecologic oncology that meets *all* of the following criteria:
        i. The fellowship program is at a hospital that has inpatient facilities, operative suites and diagnostic treatment facilities, outpatient facilities, and educational resources.
        ii. The fellowship program is at an institution that has a proven commitment to graduate medical education.
        iii. The fellowship program director must have current certification in the sub-specialty by the American Board of Surgery, the American Board of Obstetrics and Gynecology, or the American Osteopathic Board of Obstetrics and Gynecology.
        iv. 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.
        v. The fellowship program has the resources, including adequate clinical facilities, laboratory research facilities, and appropriately trained faculty and staff, to provide research experience.
    c. Either a formal 2-year surgical transplant fellowship or clinical experience meeting the requirements for the primary transplant surgeon of a kidney, liver, intestine, or pancreas transplant program as outlined in Appendices E, F, or G.
    d. Completion of at least 2 uterus transplants within the last five years as the primary surgeon or co-surgeon. This includes completion of pre-operative assessments and post-operative care for a minimum of 90 days after surgery. These transplants must be documented in a log that includes the date of the transplant, the role of the surgeon in the transplant, 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.

e. Completion of at least 15 radical hysterectomies within the last five years as the primary surgeon. 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.

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

~~D~~ E. Additional Primary Surgeon Requirements for Other VCA Transplant Programs

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

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

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

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 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.

c. Provide to the OPTN ~~Contractor~~ two letters of recommendation from directors of designated VCA transplant programs not employed by the applying hospital. These letters must address:
   i. Why an exception is reasonable.
   ii. The surgeon's overall qualifications to act as a primary VCA transplant surgeon.
   iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
   iv. Any other matters judged appropriate.

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

2. Have observed at least 2 multi-organ procurements. These observations must be documented in a log that includes the date of procurement and Donor ID.

~~2.~~ 3. Have performed the pre-operative evaluation of at least 3 potential VCA transplant patients.

~~3.~~ 4. Have current working knowledge in the surgical specialty, defined as independent practice in the specialty over a consecutive five-year period.

~~4.~~ 5. Have assembled a multidisciplinary surgical team that includes specialists necessary to complete the VCA transplant including, for example, plastic surgery, orthopedics, otolaryngology, obstetrics and gynecology, urology, or general surgery. The team must have demonstrated detailed planning that is specific for the type of VCA transplant the program will perform.

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

A letter from the presiding executive of the transplant hospital where the VCA transplant will be performed must provide written verification that requirements 1 through 4~~5~~ above have been met by the primary surgeon.

J.3 Primary VCA Transplant Physician Requirements

Each designated VCA transplant program must have a primary transplant physician who meets at least *one* of the following requirements:

- Is currently the primary transplant surgeon or primary transplant physician at a designated transplant program
- Fulfills the requirements of a primary transplant surgeon or primary transplant physician at a designated transplant program according to the OPTN Bylaws
- Is a physician with 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 and who meets *all* of the following additional requirements:

1. The physician must be accepted onto the hospital's medical staff, and be on-site at this hospital.
2. The physician must have documentation from the hospital's credentialing committee that it has verified the physician's state license, board certification, training, and transplant continuing medical education, and that the physician is currently a member in good standing of the hospital's medical staff.
3. The physician must have completed an approved transplant fellowship in a medical or surgical specialty. Approved transplant fellowships for each organ are determined according to the requirements in OPTN Bylaws *Appendices E* through *I*.
4. The physician must have current board certification by the American Board of Medical Specialties or the Royal College of Physicians and Surgeons of Canada.

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

- Be ineligible for American board certification.
- Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the physician obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are

relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.

- Provide to the OPTN ~~Contractor~~ two letters of recommendation from directors of designated transplant programs not employed by the applying hospital. These letters must address:
  i. Why an exception is reasonable.
  ii. The physician's overall qualifications to act as a primary VCA transplant physician.
  iii. The physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
  iv. Any other matters judged appropriate.

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

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

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

1. Has an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction
2. Is accepted onto the hospital's medical staff, and is on-site at this hospital.
3. Has 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.
4. Has current board certification in obstetrics and gynecology by the American Board of Obstetrics and Gynecology, the American Osteopathic Board of Obstetrics and Gynecology, or the Royal College of Physicians and Surgeons of Canada.

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

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

J.5 Uterus Transplant Programs That Perform Living Donor Recovery

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

A. Living Donor Medical Evaluation

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

B. Living Donor Psychological Evaluation

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

C. Independent Living Donor Advocate (ILDA)

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*.

D. Living Donor Uterus Surgeon Requirements

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, by completion of at least 10 radical hysterectomies, living donor uterus recoveries, or some combination thereof, within the last five years. At least 2 of these 10 procedures must be living donor uterus recoveries performed as primary surgeon or co-surgeon. These procedures must be documented in a log that includes the date of the surgery, the role of the surgeon in the procedure, and the medical record number of other unique identifier that can be verified by the OPTN.

Appendix N: Definitions

C

Covered Vascularized Composite Allograft body parts (covered VCAs)

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~~
Uterus, cervix, and vagina	Uterus
Penis and scrotum	External male genitalia
Internal male genitalia; external and internal female genitalia other than uterus, cervix, and vagina; and urinary bladder	Other genitourinary organ
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

D

Designated Transplant Program

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