

Notice of OPTN Policy & Bylaw Changes

Establish Membership Requirements for Uterus Transplant Programs

Sponsoring Committee:	Vascularized Composite Allograft Transplantation
Policies Affected:	<i>1.2: Definitions</i> <i>2.2: OPO Responsibilities</i> <i>5.4.B: Order of Allocation</i> <i>5.6.A: Receiving and Reviewing Organ Offers</i> <i>18.1: Data Submission Requirements</i> <i>18.2: Timely Collection of Data</i> <i>18.3: Recording and Reporting the Outcomes of Organ Offers</i>
Bylaws Affected:	<i>Appendix J: Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs</i> <i>Appendix N: Definitions</i>
Public Comment:	August 3, 2021 – September 30, 2021
Executive Committee Approved:	December 6, 2021
Effective Date:	Effective February 1, 2022 and Pending implementation and notice to OPTN members

Purpose of Policy and Bylaw Changes

The policy changes include a technical correction to add clarity to existing language in *Policies 2.2 OPO Responsibilities, 18.1 Data Submission Requirements, 18.2 Recording and Reporting the Outcomes of Organ Offers, and 18.3 Recording and Reporting the Outcomes of Organ Offers* by removing the word “covered” from “covered VCA” references because these are “exclusionary” versus “inclusionary” policies. These changes will be effective February 1, 2022.

The bylaw changes establish uterus, external male genitalia, and other genitourinary organs as new VCA transplant program types. Additionally, the changes establish tailored membership requirements for uterus transplant programs, including requirements for the primary surgeon, primary obstetrician-gynecologist. Living donor uterus component requirements will also be established for programs that intend to perform living donor recovery of uteri. Finally, the changes include a small number of administrative updates to clarify the current membership requirements for “other VCA” transplant programs.

Proposal History

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. These changes focus on requirements for uterus transplant programs because it is the most frequently occurring genitourinary organ transplant, with 33 transplants

performed as of December 2021.¹ Additionally, the volume of uterus transplants performed is expected to grow, given significant interest from both potential recipients and potential living donors.² For the purposes of OPTN Policy, “uterus” is defined 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.³

To develop the 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.

Summary of Changes

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.⁴

The changes include:

1. Establishment of uterus, external male genitalia, and other genitourinary organs as separate VCA transplant program types
2. Specifying requirements for uterus key personnel and programs, including living donor component requirements and the establishment of a new primary obstetrician-gynecologist position
3. Administrative changes to clarify membership requirements for “other VCA” transplant programs
4. Technical corrections to add clarity to existing policy language

Implementation

The technical corrections to *Policy 2.2: OPO Responsibilities*, *5.4.B: Order of Allocation*, *5.6.A: Receiving and Reviewing Organ Offers*, *5.6.B: Time Limit for Review and Acceptance of Organ Offers*, *18.1: Data Submission Requirements*, *18.2: Timely Collection of Data*, and *18.3: Recording and Reporting the Outcomes of Organ Offers* are effective February 1, 2022.

In preparation for implementation, current VCA genitourinary programs will be required to reapply to the OPTN designating their program as either uterus, male external genitalia, or other genitourinary organs. Revisions to the current VCA membership application will need to be approved by the Office of Management and Budget (OMB) prior to implementation. A 30-day notice will be sent to all currently approved VCA genitourinary transplant programs that new applications will be coming and must be completed. Once applications are sent to members, VCA transplant programs will need to indicate their desire to “opt out”, or will need to submit a completed application within 120 days. Transplant hospitals

¹ OPTN data as of December 9, 2021.

² Living Donor Committee Meeting Summary, May 12, 2021, OPTN, accessed June 24, 2021, https://optn.transplant.hrsa.gov/media/4656/20210512_ldc_summary.pdf.

³ BP Jones, NJ Williams, S Saso, et al., “Uterine transplantation in transgender women,” *BJOG* 126 (2019): 152-156, doi:10.1111/1471-0528.15438.

⁴ “Strategic Plan 2021-2024,” OPTN, accessed June 24, 2021, <https://optn.transplant.hrsa.gov/media/4632/optn-strategic-plan-2021-2024.pdf>.

with approved VCA genitourinary transplant programs who will be applying for uterus transplant programs will be responsible for proposing individuals who will qualify for key personnel positions. If these key personnel are U.S. board ineligible, these individuals will be responsible for adhering to the requirements of the CME pathway identified in their application.

Table 1: New VCA Program Membership Application Requirements

Program Type	Application Requirement
Uterus	Any interested transplant hospital, even if there is a currently approved “VCA – Genitourinary Organs” program in place must apply to show they will meet the new bylaw requirements upon implementation.
Male External Genitalia	Any currently approved “VCA – Genitourinary Organs” programs that still have the same resources and primary personnel in place will only need to indicate the type of genitourinary organs they intend to transplant. Non-approved VCA – Genitourinary Organs programs will have to apply.
Other Genitourinary Organs	Any currently approved “VCA – Genitourinary Organs” programs that still have the same resources and primary personnel in place will only need to indicate the type of genitourinary organs they intend to transplant. Non-approved VCA – Genitourinary Organs programs will have to apply.

Affected Policy Language

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

1.2 Definitions

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

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Covered Vascularized Composite Allograft body parts (covered VCAs)

The body parts listed below are covered VCAs. Covered VCAs are VCAs that are subject to OPTN Policies and Bylaws. Covered VCAs are categorized by type as follows:

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

2.2 OPO Responsibilities

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

[...]

11. Executing the match run and using the resulting match for each deceased donor organ allocation. The previous sentence does not apply to ~~covered~~ VCA transplants; instead, members must allocate covered VCAs according to *Policy 12.2: VCA Allocation*.

[...]

5.4.B Order of Allocation

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

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

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

5.6.A Receiving and Reviewing Organ Offers

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

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

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

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

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

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

- An organ offer acceptance
- An organ offer refusal

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

- An organ offer acceptance
- An organ offer refusal

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

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

18.1 Data Submission Requirements

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

Table 18-1: Data Submission Requirements⁵

The following member:	Must submit the following materials to the OPTN:	Within:	For:
Recovery Hospitals	<i>Living donor feedback</i>	The time prior to donation surgery	Each potential living donor organ recovered at the hospital This does not apply to covered VCA donor organs

⁵ This table has been truncated to show only the rows that have proposed changes to the policy language. Language not presented here will not be affected by this proposal.

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

18.2 Timely Collection of Data

Table 18-2: Timely Data Collection

Information is timely if this Member:	Collects this information for this form:	Within this time period:
Transplant hospital	<i>Organ specific transplant recipient registration (TRR)</i>	When the transplant recipient is discharged from the hospital or 42 days following the transplant date, whichever is first
Recovery hospital	<i>Living donor registration (LDR)</i>	When the living donor is discharged from the hospital or 42 days following the transplant date, whichever is first This does not apply to covered VCA transplants.

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

18.3 Recording and Reporting the Outcomes of Organ Offers

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

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

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

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

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Affected Bylaw Language

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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. 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. 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 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 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. This log must be signed by the program director, division chief, or department chair where the experience was gained. Surgery of the hand includes only those procedures performed on the upper limb below the elbow.

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

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

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

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

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

- 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 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:
 - i. Why an exception is reasonable.
 - ii. The surgeon's overall qualifications to act as a primary uterus 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 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 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.
- 3. 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 subspecialty 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 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 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.~~ 3. Have performed the pre-operative evaluation of at least 3 potential VCA transplant patients.
- ~~3-4.~~ 4. Have current working knowledge in the surgical specialty, defined as independent practice in the specialty over a consecutive five-year period.
- ~~4-5.~~ 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. 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 45 above have been met by the primary surgeon.

[...]

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 Psychosocial 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, within the last five years, of at least 10 radical hysterectomies, living donor uterus recoveries, or some combination thereof.

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

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

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.

Appendix N: Definitions

C

Covered Vascularized Composite Allograft body parts (covered VCAs)

The body parts listed below are covered VCAs. Covered VCAs are VCAs that are subject to OPTN Policies and Bylaws. 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

Covered VCA(s)	Type:
Abdominal wall, symphysis pubis, and any group of vascularized skeletal elements of the pelvis	Abdominal wall
Uterus, internal and external male and female genitalia, and urinary bladder	Genitourinary organ
<u>Uterus, cervix, and vagina</u>	<u>Uterus</u>
<u>Penis and scrotum</u>	<u>External male genitalia</u>
<u>Internal male genitalia; external and internal female genitalia other than uterus, cervix, and vagina; and urinary bladder</u>	<u>Other genitourinary organ</u>
Adrenal and thymus	Vascularized gland
Pelvic structures that are attached to the lower limb and transplanted intact, gluteal region, vascularized bone transfers from the lower extremity, toe transfers, and any group of vascularized body parts from the lower limb	Lower limb
Spine axis, chest wall, and other composite graft of vascularized muscle, bone, nerve, or skin	Musculoskeletal composite graft segment
Spleen	Spleen

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.

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