Guide to completing the VCA Membership Application

These instructions are intended to provide guidance on completion of an Organ Procurement and Transplantation Network Vascularized Composite Allograft (VCA) Membership Application for the purposes of Bylaw Implementation in June 2021. The VCA Membership Application separates the eight types of VCA transplant programs and also establishes the primary personnel requirements for each program.

If you have questions at any point in the VCA reapplication process, or if you are unable to find answers to within this guidance document, please contact UNOS Membership at membershiprequests@unos.org.

Background

Current OPTN Bylaws, found in Appendix J.1, Letter of Notification, only require VCA transplant programs to submit a letter to the OPTN stating intent to transplant specific VCA types.

New VCA Bylaws, however, will require specific proof of experience for both Primary Surgeons and Primary Physicians involved in the VCA transplant programs, in addition to an assessment of all surgeons and physicians involved in each program and details on each program’s coverage. Information on the evolution of the VCA Bylaws can be found on the OPTN website in a combined policy notice.

Based on the revisions to the list of covered body parts pertaining to VCA in OPTN Policy, moving forward there will now be eight different VCA transplant programs. The experience requirement for primary surgeons and physicians varies depending on VCA program.

The following body parts are considered VCAs:

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

The 120-day application period for VCA Bylaw Implementation begins Oct. 8, 2020 and ends Feb. 5, 2021. If you have a currently-approved VCA transplant program, you must reapply using the new application by the Feb. 5 deadline.

Can only existing VCA programs be approved?

If you do not currently have a VCA transplant program and wish to start one prior to the June 2021 Bylaw Implementation, please contact the United Network for Organ Sharing Membership Team at membershiprequests@unos.org for more information.

For existing VCA transplant programs

On Oct. 8, 2020, all Primary VCA Program Administrators, OPTN Representatives and OPTN Alternate Representatives will be sent separate emails for each of the VCA types they are currently approved to transplant. The email includes:

- A fillable PDF version of the VCA application
- A fillable Excel log to help track experience where requested
- The Certificate of Assessment and Program Coverage Plan form. Details on these materials are below.
- The Transplant Hospital application. Details on this application may also be found below.

In order to continue transplanting VCA, all currently-approved VCA programs must use these forms to reapply for each and any of the eight VCA program types they wish to continue. If you do not wish to continue a given VCA transplant program, you may opt out from applying. More information on opting out from applying may be found below.

What’s involved with the application?

A Membership Application consists of a series of questions aimed at understanding how applicants meet the minimum qualifications of the Bylaws to be considered for approval into the OPTN.

These applications usually consist of questions about facilities, resources, and the primary personnel who oversee the organization. They will also ask for supplemental materials, such as letters and logs that will support the claims made within the application.

For purposes of VCA Bylaw Implementation, your application will be reviewed first by a UNOS Membership Analyst. Once the application is deemed complete, it will be posted for peer review by a subcommittee of the Membership and Professional Standards Committee (MPSC). After that, the full MPSC will make the recommendation to the Board of Directors for final approval.
All logs, where applicable, must be signed by the program director, division chief, or department chair where the experience was gained. These signatures may also be captured in the signature spaces on the front page of the application.

There is an additional section of the Membership Application called the Certificate of Assessment and Program Coverage Plan, which accompanies the program application. This application is aimed at ensuring a program is adequately staffed and patients are aware of the staffing at any given transplant program. For more information, please refer to sections D.7.A. Primary Transplant Surgeon and Physician, and D.7.B. Surgeon and Physician Coverage (Program Coverage Plan) of the OPTN Bylaws. Details on completing this portion of the application are also found below.

Finally, you will receive a copy of the OPTN Membership Application for Transplant Hospitals. This application includes questions about the program’s facilities and resources, as well as the personnel that support your VCA program. Specific information on this requirement can be found below.

**How do I opt out?**

If you have a currently-approved VCA program, this approval is valid until the implementation of the new VCA Bylaws in June 2021. If you opt out from applying under the proposed Bylaws, you may still continue to transplant the VCA types you have been approved to transplant up until the Board implements the new Bylaws.

If you wish to discontinue your VCA program now, or if you have any other questions about Bylaw implementation, please contact UNOS Membership by emailing [membershiprequests@unos.org](mailto:membershiprequests@unos.org).
Directions

Who is required to sign the application forms?

According to OPTN Bylaws, Appendix A.1 Applying for Membership in the OPTN, “Applications for OPTN Membership and designated transplant program approval must be submitted on the form provided by the OPTN Contractor [UNOS] and signed by a representative of the applicant who can certify that the information, including any supporting documents, is accurate.”

The representative we look for to sign Membership applications is known as the OPTN Representative. This individual is already designated at your transplant hospital and will be indicated in the Oct. 8 email that marks the start of the 120-day application period. If you are unsure of your transplant hospital’s OPTN Representative, please reach out to the UNOS Membership team.

There are also signature spaces for Program Directors and the proposed Primary Surgeon and proposed Primary Physician. If the application requires a signature on a log, please have the individual sign in the spaces provided.

Part 1: General Information

Fill out all required fields of Part 1. Please indicate all of the VCA programs you wish to seek approval for using the checkboxes on the application:

Please note that you may use one application to apply for multiple VCA transplant programs only if you are proposing the same primary surgeon and primary physician for all programs for which you are applying. If you are proposing different primary surgeons and primary physicians for different VCA transplant programs, you must complete a new VCA application per program.
Part 2: Program Director

For this section, please indicate at least one surgeon or physician who will serve in this role per VCA program. Please make sure that for every VCA program applied for there is at least one Program Director that corresponds with that VCA type.

If more space is needed beyond what is provided on the application, please duplicate the page or attach a list of all program directors and corresponding VCA types. Indicate whether the Program Director is the existing Program Director for VCA or a newly-named director for each VCA program.

Please also be sure to include the CV of each individual named as Program Director. If the same individual who is your program director is also either your proposed primary surgeon or primary physician for any given program, you only need to attach one copy of that individual’s CV.

Parts 3 and 4: Primary Program Administrator and Primary Data Coordinator

These sections of the application ask for the respective administrative and data leads of the program. Please fill out the fields requested.

If you have different Primary Program Administrators and Primary Data Coordinators for the different VCA programs you are applying, please duplicate the page or indicate on a separate
attachment the names of these individuals, the VCA programs they are affiliated with, and the requested contact information.

**Part 5: Primary Surgeon**

Part 5 is the Primary Surgeon requirements portion of the application. Please go through the questions and answer accordingly, as well as provide the required attachments to prove surgeon experience. The following attachments are required for all proposed Primary Surgeons:

- A copy of the proposed primary surgeon’s resume/CV (Question 2a)
- A letter from the hospital credentialing committee (Question 2b)
- A log\(^1\) that shows at least two multi-organ procurements (Question 3) *Note: this log does not need to be signed.*

Once you get to Question 4 in Part 5, indicate the surgeon **pathway** respective to each and every VCA transplant program for which the surgeon is being proposed as Primary Surgeon.

For example, if the surgeon is being proposed for Upper Limb and Lower Limb VCA transplant programs, you would check the boxes next to “Upper Limb” and “Genitourinary Organs, Glands, Lower Limb, Musculoskeletal, and Spleen Transplants” in question 4. Then you would complete Section 4A, which corresponds to Upper Limb, and Section 4D, which corresponds to Lower Limb.

The following sections will cover the specific pathways for Primary Surgeon.

*Section 4A: Upper Limb*

This pathway contains Primary Surgeon requirements for an Upper Limb VCA transplant program. Question 1 asks about board certification, or its equivalent if the proposed primary surgeon is not board certified. Question 2 asks about the surgeon’s training or experience in hand surgery.

*Section 4B: Head and Neck*

This section includes Primary Surgeon requirements for a Head and Neck VCA transplant program. Question 1 asks about board certification. Question 2 asks about the surgeon’s training or experience in otolaryngology, plastic, oral and maxillofacial, or craniofacial surgery.

\(^1\) For any section of the VCA application that requires a log, please use the Surgeon or Physician Log form that is available on the UNOS website at [https://unos.org/community/members/how-to-apply/](https://unos.org/community/members/how-to-apply/). The log is specially-designed to capture VCA experience requirements. If you choose not to use the log provided by UNOS, please enter required experience on a separate attachment that includes all of the information requested.
Section 4C: Abdominal Wall

This section contains additional Primary Surgeon requirements for Abdominal Wall VCA transplant programs. In this section, please indicate if the proposed surgeon already meets the qualifications of either Section 4A or 4B in this application or primary surgeon requirements for intestine, kidney, liver, or pancreas transplant programs.

If the proposed surgeon is already the approved primary of any of these organ transplant programs, the UNOS Membership team will verify that information is correct.

IMPORTANT: If the proposed Primary Surgeon is not a current Primary Surgeon for any one of the indicated programs, they must complete an application for one of the organs to prove they are eligible for abdominal wall transplantation. This application will need to be reviewed as part of the abdominal wall VCA program application. Please request the appropriate application and complete it as soon as possible to avoid any delays in processing.

Section 4D: Genitourinary Organs, Glands, Lower Limb, Musculoskeletal, and Spleen

This section covers additional primary surgeon requirements for Genitourinary, Glands, Lower Limb, Musculoskeletal, and Spleen VCA transplant programs. In addition to the certification question, the proposed primary surgeon must provide:

- A log of at least three VCA pre-operative evaluations
- Documentation that supports the proposed primary surgeon’s working knowledge of the surgical specialty relative to the VCA type, over a consecutive five-year period
- Proof that the proposed primary surgeon assembled a multidisciplinary team with experience specific to the VCA type to be transplanted
- A log containing one of the team member’s microvascular experience such as replantation, revascularization, free tissue transfer or major flap surgery
- A letter from the presiding executive of the transplant hospital where the VCA transplants will be performed

Part 6: Primary Physician

This section covers the Primary Physician requirements for any VCA program type. Within this section, which is applicable to any VCA program, the proposed primary physician must meet at least one of the following:

1) Indicate whether they are the current Primary Surgeon or Primary Physician for another designated transplant program at the transplant hospital
2) Show that they meet the requirements of a Primary Surgeon or Primary Physician though they are not the approved Primary Surgeon or Primary Physician of a designated transplant program.

**IMPORTANT:** if you are proposing a Primary Physician that is not a currently-approved Primary Surgeon or Primary Physician but fulfills the requirements for a Primary Surgeon or Primary Physician, you must submit an application that proves the individual is qualified to be either the Primary Surgeon or Primary Physician for a transplant program according to the OPTN Bylaws. This application will need to be reviewed as part of the VCA program application. Please request the appropriate application and complete it as soon as possible to avoid any delays in processing.

3) Answer a series of questions that demonstrates their board certification (or equivalent), hospital credentials, and proof of fellowship in a medical or surgical specialty from an approved fellowship program as indicated under Appendices E-I in the OPTN Bylaws.
Certificate of Assessment and Program Coverage Plan

Separate from the VCA Membership Application, the Certificate of Assessment and Program Coverage Plan is designed to account for all of the program’s surgeons and physicians while ensuring the transplant program is adequately staffed to serve its patients.

For every VCA program for which the transplant hospital is applying, there must be an accompanying Certificate of Assessment and Program Coverage Plan Membership Application completed.

Who is required to sign the application forms?

According to OPTN Bylaws, Appendix A.1 Applying for Membership in the OPTN, “Applications for OPTN Membership and designated transplant program approval must be submitted on the form provided by the OPTN Contractor [UNOS], and signed by a representative of the applicant who can certify that the information, including any supporting documents, is accurate.”

This form must be signed by the OPTN Representative, the program directors, the proposed primary surgeon and proposed primary physician of the VCA program.

Part 1: General Information

Complete all of the fields in the section. For the question, “This application corresponds with” select “VCA” from the drop down menu.

Part 2: Certificate of Assessment

According to Appendix D.7.A Primary Transplant Surgeon and Physician:

“As part of the plan for continuing policy compliance that is required in the membership application, each primary surgeon or primary physician will submit an assessment of all physicians and surgeons in the program. This assessment must include any involvement in prior transgressions of OPTN obligations and plans to ensure compliance. This information is subject to medical peer review confidentiality requirements and must be submitted according to the guidelines provided in the application and to the satisfaction of the Membership and Professional Standards Committee (MPSC).”

List all of the surgeons and physicians involved in the VCA program. Use the dropdown boxes to indicate whether the surgeon or physician listed is the Primary, Additional, or Other. Definitions on each type of personnel are located on the application.
If any of the personnel listed have transgressions with the OPTN, please indicate on the application by selecting ‘Yes’ and provide an explanation in the space below the table to ensure ongoing compliance.

Part 3: Program Coverage Plan

According to Appendix D.7.B Surgeon and Physician Coverage (Program Coverage Plan):

“The Program Coverage Plan must describe how continuous medical and surgical coverage is provided by transplant surgeons and physicians who have been credentialed by the transplant hospital to provide transplant services to the program.”

The first question involves an attestation that the program provides patients with a written copy of the Program Coverage Plan. Check the box to attest.

Depending on how the questions are answered in the Program Coverage Plan, provide the requested supplemental material. If your VCA program is a single surgeon and/or physician program, provide a copy of the patient notification or your program’s protocols that displays the patient notification.

All programs completing this Program Coverage Plan portion of the application will need to submit a copy of their Program Coverage Plan. The Program Coverage Plan must include the
notifications that patients receive when they are placed on the waiting list and when there are any substantial changes in the program or its personnel.

Transplant Hospital Application

Who is required to sign the application forms?

According to OPTN Bylaws, Appendix A.1 Applying for Membership in the OPTN, “Applications for OPTN Membership and designated transplant program approval must be submitted on the form provided by the OPTN Contractor [UNOS], and signed by a representative of the applicant who can certify that the information, including any supporting documents, is accurate.”

This form must be signed by the OPTN Representative at the transplant hospital.

Part 1: General Information

Complete all of the fields in the section. For the question, “This application corresponds with” select “VCA” from the drop down menu.

Part 2: Designated Transplant Program Requirement

Check all boxes that apply to the transplant hospital that will house the VCA program.

Part 3: Facilities and Resources

For Question 1, please provide an executive summary of the VCA program’s physical space. This includes operating and recovery room resources, intensive care resources, and surgical beds.

For Questions 2 through 5, please check ‘yes’ or ‘no’ to each question. These questions are aimed at understanding how the transplant hospital and program meets geographic requirements.

Question 6 asks for a map of the transplant hospital that show where the transplant program and its ORs are located within the hospital campus. Some applicants use the hospital map provided to patients or employees to help them navigate around the campus, and highlight the locations of the transplant program and its ORs.

Question 7 asks for all letters of agreement or contracts with OPO Members for VCA. A new OPO agreement is not necessary if one is on file. Please note that if you have an already-approved VCA program or programs already, then you likely have an existing OPO agreement on file. Please contact UNOS Membership if you have questions about this specific requirement.

Question 8 asks for the lab agreement between the VCA program and an OPTN-approved histocompatibility laboratory.

Question 9 features a text box where you may list all local blood banks that interact with the transplant hospital.
Question 10 has a text box where you list all laboratories that interact with the transplant hospital.

**Part 4: Quality Assessment and Performance (QAPI) Requirement**

In this section, you will check the boxes to attest that your transplant hospital has a QAPI plan. Please provide any QAPI plan documentation you have to support this claim with the application.

**Part 5: Additional Transplant Program Personnel**

For Questions 1 through 3, in the spaces provided, please provide the name of at least one of each of the following:

- Clinical Transplant Coordinator for the VCA program
- Financial Coordinator for the transplant hospital
- Clinical Transplant Pharmacist for the VCA program

Question 4 is asking for a list of transplant program collaborators from a list of disciplines. Please provide this list on a Word, Excel, or PDF document.

Question 5 similarly asks for a list of all mental health and social support staff for the VCA program. To better understand what each of these individuals do for the program, please include any job descriptions from these individuals.

**Part 6: Donation after Circulatory Death (DCD) Protocols**

For this part, please provide the transplant hospital’s DCD recovery protocols.

**Contact**

If you have any question about the VCA application as you work through them, please contact the UNOS Membership Team at membershiprequests@unos.org or by calling 833-577-9469.