

OPTN Membership Application for Vascularized Composite Allograft (VCA) Transplant Programs

CERTIFICATION

The undersigned, a duly authorized representative of the applicant, does hereby certify that the answers and attachments to this application are true, correct and complete, to the best of his or her knowledge after investigation. I understand that the intentional submission of false data to the OPTN may result in action by the Secretary of the Department of Health and Human Services, and/or civil or criminal penalties. By submitting this application to the OPTN, the applicant agrees: (i) to be bound by OPTN Obligations, including amendments thereto, if the applicant is granted membership and (ii) to be bound by the terms, thereof, including amendments thereto, in all matters relating to consideration of the application without regard to whether or not the applicant is granted membership.

If you have any questions, please call the UNOS Membership Team at 833-577-9469 or email MembershipRequests@unos.org.

OPTN Representative

Printed Name	Signature	Email Address
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Program Director for _____	VCA Type
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Printed Name	Signature	Email Address
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Program Director for _____ (if applicable)	VCA Type
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Printed Name	Signature	Email Address
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Program Director for _____ (if applicable)
VCA Type

Printed Name	Signature	Email Address
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Program Director for _____ (if applicable)
VCA Type

Printed Name	Signature	Email Address
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Proposed Primary Surgeon for _____
VCA Type

Printed Name	Signature	Email Address
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Proposed Primary Physician for _____
VCA Type

Printed Name	Signature	Email Address
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Part 1: General Information

Name of Transplant Hospital: _____

OPTN Member Code (4 Letters): _____

Transplant Program Office Address

Street: _____ Ste: _____ Phone #: _____

City: _____ ST: _____ Zip: _____ Fax #: _____

Name of Person Completing Form: _____ Title: _____

Email Address of Person Completing Form: _____

Date Form is submitted to OPTN Contractor: _____

Indicate which VCA program(s) the hospital is applying for OPTN Membership:

- ☐ Upper Limb
- ☐ Head and Neck
- ☐ Abdominal Wall
- ☐ Genitourinary Organs
- ☐ Glands
- ☐ Lower Limb
- ☐ Musculoskeletal
- ☐ Spleen

Part 2: Program Director(s)

A VCA transplant program must identify at least one designated staff member to act as the VCA program director. The director must be a physician or surgeon who is a member of the transplant hospital staff. The same individual can serve as the program director for multiple VCA programs.

Name of Program Director(s) (list all):		New	Existing
For _____	_____	<input type="checkbox"/>	<input type="checkbox"/>
VCA Type	Name		
For _____	_____	<input type="checkbox"/>	<input type="checkbox"/>
VCA Type	Name		
For _____	_____	<input type="checkbox"/>	<input type="checkbox"/>
VCA Type	Name		
For _____	_____	<input type="checkbox"/>	<input type="checkbox"/>
VCA Type	Name		

Include the resume/CV of each individual listed.

Part 3: Primary Program Administrator

A primary program administrator is the identified administrative lead for the transplant program.

Name of Primary Program Administrator:

Credentials:

Title at Hospital:

Phone Number:

Email:

Part 4: Primary Data Coordinator

A primary data coordinator is the identified data lead for the transplant program.

Name of Primary Data Coordinator:

Credentials:

Title at Hospital:

Phone Number:

Email:

Part 5: Primary VCA Transplant Surgeon Requirements

1. Name of Proposed Primary VCA Transplant Surgeon (as indicated in Certificate of Assessment):

Name	NPI #
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2. Check yes or no for each of the following. Provide documentation where applicable:

Yes No

- ☐ ☐ 2a. Does the surgeon 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?

Provide a copy of the surgeon's resume/CV.

- ☐ ☐ 2b. Has the surgeon been accepted onto the hospital's medical staff, and is practicing on site at this hospital?

Provide documentation from the hospital credentialing committee that it has verified the surgeon's state license, board certification, training, and transplant continuing medical education, and that the surgeon is currently a member in good standing of the hospital's medical staff.

3. The surgeon must have observed **at least 2** multi-organ procurements.
This experience must be documented on the log provided.

4. Which of the following VCA programs is the proposed primary surgeon applying? (check all that apply, and complete the corresponding additional requirements below):

- ☐ **Upper Limb**, as described in Part 4Error: Reference source not found below.
- ☐ **Head and Neck**, as described in Part 4B: Additional Primary Surgeon Requirements for Head and Neck Transplant Programs below.
- ☐ **Abdominal Wall**, as described in part 4Error: Reference source not found below.
- ☐ **Genitourinary Organs, Glands, Lower Limb, Musculoskeletal, and Spleen Transplants**, as described in Part 4D: Additional Primary Surgeon Requirements for Genitourinary Organs, Glands, Lower Limb, Musculoskeletal, and Spleen Transplant Programs below.

4A: Additional Primary Surgeon Requirements for Upper Limb Transplant Programs

1. Certification. Check one and provide corresponding documentation:

- ☐ a. The surgeon is currently certified 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.

Provide a copy of the surgeon's current board certification.

- ☐ b. The surgeon has just completed training and is 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. Therefore, the surgeon is requesting conditional approval for 24 months to allow time to complete board certification, with the possibility of renewal for one additional 16-month period.

Provide documentation supporting that training has been completed and certification is pending, which must include the anticipated date of board certification and where the surgeon is in the process to be certified.

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

This experience must be documented on the log provided.

- ☐ d. The surgeon is without certification from 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.
- If this option is selected:
- **The surgeon must be ineligible for American board certification. If not eligible, provide an explanation why the individual is ineligible:**

 - **Provide a plan for continuing education that is comparable to American board maintenance of certification; and**
 - **Provide at least 2 two letters of recommendation from directors of designated transplant programs not employed by the applying hospital that address**
 - o **why an exception is reasonable,**
 - o **the individual's overall qualifications to act as a primary upper limb transplant surgeon,**
 - o **the individual's personal integrity and honesty,**
 - o **the individual's familiarity with and experience in adhering to OPTN obligations and compliance protocols, and**
 - o **any other matters judged appropriate.**

2. At least one of the following must be completed by the surgeon. **Check all that apply:**

- ☐ Accreditation from Accreditation Council of Graduate Medical Education (ACGME) approved fellowship program in hand surgery.
Provide a copy of ACGME accreditation with the application.

- ☐ **A fellowship program in hand surgery that meets all of the following criteria:**
- The program is at a hospital that has inpatient facilities, operative suites and diagnostic treatment facilities, outpatient facilities, and educational resources.
 - The program is at an institution that has a proven commitment to graduate medical education.
 - 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.
 - 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.
 - The program is at a hospital that has affiliated rehabilitation medicine services.
 - The program has the resources, including adequate clinical facilities, laboratory research facilities, and appropriately trained faculty and staff, to provide research experience.
- Provide a written explanation of the fellowship program demonstrating that it included all of the above. Submit as an attachment to the application.**

- ☐ **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 shown in Table 1 below.** This includes completion of pre-operative assessments and post-operative care for a minimum of 90 days after surgery. Surgery of the hand includes only those procedures performed on the upper limb below the elbow.

This experience must be documented on the log provided.

Table 1: Minimum Procedures for Upper Limb Primary Transplant Surgeons

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

4B: Additional Primary Surgeon Requirements for Head and Neck Transplant Programs

In addition to the primary VCA transplant surgeon requirements listed above, the transplant surgeon for a head and neck transplant program must meet *both* of the following:

1. **Certification. Check one and provide corresponding documentation:**

- ☐ a. The surgeon is currently certified 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.
Provide a copy of the surgeon's current board certification.
- ☐ b. The surgeon has just completed training and is 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. Therefore, the surgeon is requesting conditional approval for 24 months to allow time to complete board certification, with the possibility of renewal for one additional 16-month period.
Provide documentation supporting that training has been completed and certification is pending, which must include the anticipated date of board certification and where the surgeon is in the process to be certified.
- ☐ c. 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:
- Acted as the first-assistant or primary surgeon on **at least 1** VCA procurement.
 - Participated in the pre-operative evaluation of **at least 3** potential head and neck transplant patients.
 - Acted as primary surgeon of **a least 1** head and neck transplant.
 - Participated in the post-operative follow-up of **at least 1** head and neck recipient for 1 year post-transplant.
- This experience must be documented on the log provided.**
- ☐ d. The surgeon is without certification from 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.
If this option is selected:
- **The surgeon must be ineligible for American board certification. If not eligible, provide an explanation why the individual is ineligible:**

 - **Provide a plan for continuing education that is comparable to American board maintenance of certification; and**
 - **Provide at least 2 two letters of recommendation from directors of designated transplant programs not employed by the applying hospital that address**
 - o why an exception is reasonable,
 - o the individual's overall qualifications to act as a primary head and neck transplant surgeon,
 - o the individual's personal integrity and honesty,
 - o the individual's familiarity with and experience in adhering to OPTN obligations and compliance protocols, and
 - o any other matters judged appropriate.

2. At least one of the following must be completed by the surgeon.

Check all that apply

- ☐ Any **ACGME-approved fellowship program** in otolaryngology, plastic, oral and maxillofacial, or craniofacial surgery.

Provide a copy of ACGME accreditation with the application.

- ☐ **A fellowship program in otolaryngology, plastic, oral and maxillofacial, or craniofacial surgery that meets all of the following criteria:**

- The program is at a hospital that has inpatient facilities, operative suites and diagnostic treatment facilities, outpatient facilities, and educational resources.
- The program is at an institution that has a proven commitment to graduate medical education.
- The program director must have current certification in the sub-specialty by the American Board of Plastic Surgery, the American Board of Otolaryngology, American Board of Oral and Maxillofacial Surgery.
- 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.
- The program is at a hospital that has affiliated rehabilitation medicine services.
- The program has the resources, including adequate clinical facilities, laboratory research facilities, and appropriately trained faculty and staff, to provide research experience.

Provide a written explanation of the fellowship program demonstrating that it included all of the above. Submit as an attachment to the application.

- ☐ **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 as shown in *Table 2* below. This includes completion of pre-operative assessments and post-operative care for a minimum of 90 days after surgery.

This experience must be documented on the log provided.

Table 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

4C: Additional Primary Surgeon Requirements for Abdominal Wall Transplant Programs

The primary surgeon for an abdominal wall transplant program must meet the primary transplant surgeon requirements of a head and neck, intestine, kidney, liver, pancreas, or upper limb transplant program.

Which primary surgeon requirements does the proposed abdominal wall primary surgeon meet?

(check one):

- ☐ Intestine
- ☐ Kidney
- ☐ Liver
- ☐ Pancreas
- ☐ VCA: Head and Neck
- ☐ VCA: Upper Limb

Part 4D: Additional Primary Surgeon Requirements for Genitourinary Organs, Glands, Lower Limb, Musculoskeletal, and Spleen Transplant Programs

This pathway is only for the primary transplant surgeon at a VCA transplant program intending to transplant body parts other than those that will be transplanted at approved upper limb, head and neck, or abdominal wall transplant programs. The VCA transplant program must specify the body part(s) it will transplant in the application.

1. *Which type of body parts will the VCA transplant program be transplanting?*

- ☐ Genitourinary
- ☐ Glands
- ☐ Lower Limb
- ☐ Musculoskeletal
- ☐ Spleen

In addition to the requirements as described by the primary VCA transplant surgeon requirements listed above, the primary surgeon for other VCA transplant programs must meet *all* of the following:

2. ***For the following question, check yes or no:***

Yes No

☐ ☐ Does the type of VCA transplant for which the surgeon is applying must meet all nine of the following criteria?

- a. That is vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation.
- b. Containing multiple tissue types.
- c. Recovered from a human donor as an anatomical/structural unit.
- d. Transplanted into a human recipient as an anatomical/structural unit.
- e. Minimally manipulated (i.e., processing that does not alter the original relevant characteristics of the organ relating to the organ's utility for reconstruction, repair, or replacement).
- f. For homologous use (the replacement or supplementation of a recipient's organ with an organ that performs the same basic function or functions in the recipient as in the donor).

- g. Not combined with another article such as a device.
- h. Susceptible to ischemia and, therefore, only stored temporarily and not cryopreserved.
- i. Susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.

3. **Certification. Check one and provide corresponding documentation:**

- ☐ a. The surgeon is currently certified by the American Board of Medical Specialties or Royal College of Physicians and Surgeons of Canada in a specialty relevant to the type of VCA transplant the surgeon will be performing.

Provide a copy of the surgeon's current board certification.

- ☐ b. The surgeon is without certification from American Board of Medical Specialties or Royal College of Physicians and Surgeons of Canada in a specialty relevant to the type of VCA transplant the surgeon will be performing.

If this option is selected:

- **The surgeon must be ineligible for American board certification. Provide an explanation why the individual is ineligible:**

- **Provide a plan for continuing education that is comparable to American board maintenance of certification; and**
- **Provide at least 2 two letters of recommendation from directors of designated transplant programs not employed by the applying hospital that address**
 - o **why an exception is reasonable,**
 - o **the individual's overall qualifications to act as a primary VCA transplant surgeon,**
 - o **the individual's personal integrity and honesty,**
 - o **the individual's familiarity with and experience in adhering to OPTN obligations and compliance protocols, and**
 - o **any other matters judged appropriate.**

4. *Provide proof that the surgeon has performed the pre-operative evaluation of at least 3 potential VCA transplant patients.*

This experience must be documented on the log provided.

5. *Provide proof that the surgeon has current working knowledge in the surgical specialty, defined as independent practice in the specialty over a consecutive five-year period.*

Provide a written explanation that supports this experience.

6. *Provide proof that the surgeon has 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. This team must include a team member that has microvascular experience such as replantation, revascularization, free tissue transfer, and major flap surgery. The team demonstration of detailed planning that is specific for the types of VCA transplant the program will perform.*

This experience must be documented on the log provided.

7. ***Provide a letter from the presiding executive of the transplant hospital where the VCA will be performed.*** The letter must provide written verification that requirements 1 through 5 above have been met by the primary surgeon.

Part 6: Primary VCA Transplant Physician Requirements

1. **Name of Proposed Primary VCA Transplant Physician (as indicated in Certificate of Assessment):**

Name	NPI #
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Each designated VCA transplant program must have a primary transplant physician who meets at least one of the following requirements: **(check one)**

- ☐ Is currently the primary transplant surgeon or primary transplant physician at a designated transplant program.
List the program(s) the surgeon or physician is a primary for: _____

- ☐ Fulfills the requirements of a primary transplant surgeon or primary transplant physician at a designated transplant program according to the OPTN Bylaws
List the program the surgeon or physician could be primary for: _____

A program application will be required to document how the surgeon or physician fulfills requirements.

- ☐ 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:
- The physician must be accepted onto the hospital's medical staff, and be on-site at this hospital.
Provide a copy of physician's current certification.
 - 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.
Provide documentation from the hospital 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.
 - The physician must have completed an approved transplant fellowship in a medical or surgical specialty. Approved OPTN transplant fellowships for each organ are determined according to the requirements in OPTN Bylaws.
Provide proof of the physician's fellowship.
 - 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:

- ***The physician must be ineligible for American board certification. Provide an explanation why the individual is ineligible:***

- ***Provide a plan for continuing education that is comparable to American board maintenance of certification; and***
- ***Provide at least two letters of recommendation from directors of designated transplant programs not employed by the applying hospital that address***
 - o ***why an exception is reasonable,***
 - o ***the individual's overall qualifications to act as a primary VCA transplant surgeon,***
 - o ***the individual's personal integrity and honesty,***
 - o ***the individual's familiarity with and experience in adhering to OPTN obligations and compliance protocols, and***
 - o ***any other matters judged appropriate.***

PUBLIC BURDEN STATEMENT

The private, non-profit Organ Procurement and Transplantation Network (OPTN) collects this information in order to perform the following OPTN functions: to assess whether applicants meet OPTN Bylaw requirements for membership in the OPTN; and to monitor compliance of member organizations with OPTN Obligations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0915-0184 and it is valid until XX/XX/2023. This information collection is required to obtain or retain a benefit per 42 CFR §121.11(b)(2). All data collected will be subject to Privacy Act protection (Privacy Act System of Records #09-15-0055). Data collected by the private non-profit OPTN also are well protected by a number of the Contractor's security features. The Contractor's security system meets or exceeds the requirements as prescribed by OMB Circular A-130, Appendix III, Security of Federal Automated Information Systems, and the Departments Automated Information Systems Security Program Handbook. The public reporting burden for this collection of information is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 14N136B, Rockville, Maryland, 20857 or paperwork@hrsa.gov.