

# 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.

## OPTN Representative

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Printed Name

Signature

Email Address

## Part 1: General Information

Name of Transplant Hospital: \_\_\_\_\_

OPTN Member Code (4 Letters): \_\_\_\_\_

Transplant Hospital Address (where transplants occur)

Street: \_\_\_\_\_ Suite: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

VCA Transplant Program Phone #: \_\_\_\_\_

Name of Person Completing Form: \_\_\_\_\_ Title: \_\_\_\_\_

Email Address of Person Completing Form: \_\_\_\_\_

Date Form is submitted to OPTN Contractor: \_\_\_\_\_

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

*This form should only be used to apply for one VCA program at a time.*

- |   |  |
|---|--|
| <input type="checkbox"/> Upper Limb                 | <input type="checkbox"/> Vascularized Gland              |
| <input type="checkbox"/> Head and Neck              | <input type="checkbox"/> Lower Limb                      |
| <input type="checkbox"/> Abdominal Wall             | <input type="checkbox"/> Musculoskeletal Composite Graft |
| <input type="checkbox"/> Uterus                     | <input type="checkbox"/> Segment                         |
| <input type="checkbox"/> External Male Genitalia    | <input type="checkbox"/> Spleen                          |
| <input type="checkbox"/> Other Genitourinary Organs |  |

## Part 2: Certificate of Assessment

The hospital must conduct an assessment of all transplant program surgeons and physicians for any involvement in prior transgressions of OPTN obligations and plans to ensure compliance.

The **primary surgeon** and **primary physician** are responsible for ensuring the operation and compliance of the program according to OPTN requirements. The transplant hospital must notify the OPTN Contractor immediately if at any time the program does not meet these requirements. The individuals reported to the OPTN Contractor as the program's primary surgeon and primary physician should be the same as those reported to the Center for Medicaid and Medicare Services (CMS).

**Additional Transplant Surgeons** must be credentialed by the transplant hospital to provide transplant services and be able to independently manage the care of transplant patients, including performing the transplant operations and organ procurement procedures.

**Additional Transplant Physicians** must be credentialed by the transplant hospital to provide transplant services and be able to independently manage the care of transplant patients.

A surgeon or physician employed by the transplant hospital that does not independently manage the care of transplant patients may be listed as **other**.

This information is subject to medical peer review confidentiality requirements and must be submitted according to the guidelines provided in the application.

### Instructions:

*On the next page, list all surgeons and physicians involved in the transplant program.*

- *For any surgeon or physician indicated as 'Primary' that isn't already the approved primary surgeon or primary physician for the program, complete the relevant sections of the application below.*
- *For each surgeon or physician that is newly designated as 'Additional', provide a credentialing letter with this application.*
- *For each surgeon or physician listed as 'Other', no further action is needed.*
- *If you have answered 'yes' to any surgeon or physician having prior transgressions with the OPTN, please explain in the blank space provided below the table.*

Name	NPI# (optional)	Surgeon or Physician	Primary, Additional, or Other	Main Program	Living Donor Component (Uterus Only)
					<input type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>
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Do any of the individuals listed above have OPTN transgressions? ☐ Yes ☐ No

If yes, provide the name of the individual(s) and the program's plan to ensure compliance:

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## Part 3: Program Coverage Plan

The program director, along with the primary surgeon and physician, must submit a detailed **Program Coverage Plan** to the OPTN Contactor. 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.

A transplant program must inform its patients if it is staffed by a single surgeon or physician and acknowledge the potential unavailability of these individuals, which could affect patient care, including the ability to accept organ offers, procurement, and transplantation.

### Instructions:

*Complete the questions below and provide documentation where applicable.*

## Transplant Surgeon and Physician Coverage

### Surgeons

#### Yes No

- ☐ ☐ *Is this a single surgeon program?*  
*If yes, provide a copy of the patient notice or protocol for providing patient notification.*
- ☐ ☐ *Does the transplant program have transplant surgeons available 365 days a year, 24 hours a day, 7 days a week to provide program coverage?*  
*If the answer is no, provide a written explanation in the Program Coverage Plan that justifies the current level of coverage.*
- ☐ ☐ *Is a transplant surgeon readily available in a timely manner to facilitate organ acceptance, procurement, and transplantation?*
- ☐ ☐ *Will any of the transplant surgeons be on call simultaneously at two transplant programs more than 30 miles apart?*  
*If the answer is yes, the program must request an exemption from the MPSC to operate as a transplant program sharing primary personnel with another transplant hospital, without additional transplant staff.*
- ☐ ☐ *Is the **primary** transplant surgeon designated as the primary transplant surgeon at more than one transplant hospital?*  
*If yes, answer the question below.*

Yes No

☐ ☐ Do you have additional surgeons listed with the program? **If the answer is no, the program must request an exemption from the MPSC to operate as a transplant program sharing primary personnel with another transplant hospital, without additional transplant staff.**

- ☐ ☐ Is the **primary** transplant surgeon **onsite** full-time at this transplant hospital?  
**If the answer is no, please describe in detail the onsite arrangements:**

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- ☐ ☐ Does the **primary** transplant surgeon have **on-call responsibilities** at more than one transplant hospital at the same time? **If the answer is yes, please explain below:**

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## Physicians

Yes No

- ☐ ☐ Is this a single physician program?  
**If yes, provide a copy of the patient notice or protocol for providing patient notification.**

- ☐ ☐ Does the transplant program have transplant physicians available 365 days a year, 24 hours a day, 7 days a week to provide program coverage?  
**If the answer is no, provide a written explanation that justifies the current level of coverage.**

- ☐ ☐ Will any of the transplant physicians be on call simultaneously for two transplant programs more than 30 miles apart?  
**If the answer is yes, the program must request an exemption from the MPSC to operate as a transplant program sharing primary personnel with another transplant hospital, without additional transplant staff.**

- ☐ ☐ Is the primary transplant physician designated as the primary transplant physician at more than one transplant hospital?  
**If yes, answer the question below.**

Yes No

☐ ☐ Do you have additional physicians listed with the program?  
**If the answer is no, the program must request an exemption from the MPSC to operate as a transplant program sharing primary personnel with another transplant hospital, without additional transplant staff.**

- ☐ ☐ Is the **primary** transplant physician **onsite** full-time at this transplant hospital?

***If the answer is no, please describe in detail the onsite arrangements:***

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- ☐ ☐ Does the **primary** transplant physician have **on-call responsibilities** at more than one transplant hospital at the same time?

***If the answer is yes, please explain below:***

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## **Patient Notification**

***Check the box below to attest to the following:***

- ☐ The transplant program provides patients with a written summary of the Program Coverage Plan when placed on the waiting list and when there are any substantial changes in the program or its personnel.

***Attach a copy of the Program Coverage Plan to the application.***

## Part 4: 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.

**Program Director(s) (list all):**

Name	Credentials
Name	Credentials
Name	Credentials
Name	Credentials



## Part 5: Primary VCA Transplant Surgeon Requirements

1. **Name of Proposed Primary VCA Transplant Surgeon (as indicated in Part 2: Certificate of Assessment):**

Name	NPI # (optional)
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2. **Check to attest to each of the following. Provide documentation where applicable:**

☐ *The surgeon 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*  
***Provide a copy of the surgeon's medical license and resume/CV/documentation of education to show proof of this requirement.***

☐ *The surgeon is 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. **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.
- ☐ **Uterus**, as described in Part 4D: Additional Primary Surgeon Requirements for Uterus Transplant Programs below.
- ☐ **External Male Genitalia, Other Genitourinary Organ, Vascularized Gland Lower Limb, Musculoskeletal Composite Graft Segment, and/or Spleen**, as described in Part 4E: Additional Primary Surgeon Requirements for External Male Genitalia, Other Genitourinary Organs, Vascularized Gland, Lower Limb, Musculoskeletal Composite Graft Segment, and Spleen Transplant Programs below.

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

In addition to the requirements as described above, the surgeon for an upper limb transplant program must meet *all* of the following:

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

- ☐ *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.***

- ☐ *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.***

- ☐ *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** covered 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.*

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

*In addition to the experience above, a surgeon 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 must:*

- ***Be ineligible for American board certification. If not eligible, provide an explanation why the individual is ineligible:***

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- ***Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that:***
    - o *The surgeon obtains 60 hours of Category I continuing medical education (CME) credits.*
    - o *The surgeon performs a self-assessment that is relevant to the individual's practice every three years, with a score of 75% or higher. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program.*
  - ***The transplant hospital document completion of this continuing education.***
  - ***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, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.*
    - o *Any other matters judged appropriate.*

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

- ☐ *Completion of an Accreditation Council of Graduate Medical Education (ACGME) approved fellowship program in hand surgery.*  
***Provide proof of completion of the fellowship 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.

***Provide a log of these procedures that includes the date of the procedure and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained. Surgery of the hand includes only those procedures performed on the upper limb below the elbow.***

**Table 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. The surgeon must have observed **at least 2** multi-organ procurements.  
***Provide a log of these observations that includes the date of procurement and Donor ID.***

#### **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 *all* of the following:

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

- ☐ *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.***

- ☐ *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.***

- ☐ *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 covered 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.*

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

*In addition to the above experience, a surgeon 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 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. This plan must at least require that:***
    - o *The surgeon obtains 60 hours of Category I continuing medical education (CME) credits.*
    - o *The surgeon performs a self-assessment that is relevant to the individual's practice every three years, with a score of 75% or higher. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program.*
    - o *The transplant hospital document completion of this continuing education.*
  - ***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, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.*
    - 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 proof of completion of this fellowship 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.

***Provide a log of these procedures that includes the dates of procedures and evaluations, the role of the surgeon and the medical record number, Donor ID, or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained.***

**Table 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. ***The surgeon must have observed at least 2 multi-organ procurements.***  
***Provide a log of these observations that includes the date of procurement and Donor ID.***

**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.*

1. *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*

Note: If this surgeon is not already an approved primary surgeon in the selected box above, an application proving that OPTN requirements are met must be submitted.

2. *The surgeon must have observed **at least 2** multi-organ procurements.  
Provide a log of these observations that includes the date of procurement and Donor ID*



#### **4D: Additional Primary Surgeon Requirements for Uterus Transplant Programs**

In addition to the primary VCA transplant surgeon requirements listed above, the transplant surgeon for a uterus transplant program must meet the following:

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

- ☐ *The surgeon is currently certified 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.*

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

- ☐ *The surgeon has just completed training and is pending certification 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. 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.***

- ☐ *The surgeon is without certification from 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.*

*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:***

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- ***Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that:***
  - o ***The surgeon obtains 60 hours of Category I continuing medical education (CME) credits.***
  - o ***The surgeon performs a self-assessment that is relevant to the individual's practice every three years, with a score of 75% or higher. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program.***
  - o ***The transplant hospital document completion of this continuing education.***
- ***Provide at least 2 two letters of recommendation from directors of designated VCA, kidney, liver, intestine, or pancreas 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 uterus transplant surgeon.*
- o The individual's personal integrity and honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.*
- o Any other matters judged appropriate.*

2. *The surgeon must have experience in organ procurement by meeting **either** of the following:*

- Observation or completion of at least 2 multi-organ procurements within the last 5 years.*
- Completion of one deceased donor uterus procurement as primary surgeon within the last five years.*

***Provide a log of these observations or completed procurements that includes the date of procurement and Donor ID.***

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

***Check all that apply***

- ☐ ***Any ACGME-approved fellowship program in gynecologic oncology.***

***Provide proof of completion of this fellowship with the application.***

- ☐ ***A fellowship program in gynecologic oncology 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 Surgery, the American Board of Obstetrics and Gynecology, or the American Osteopathic Board of Obstetrics and Gynecology*
- The program should have at least two physician faculty members with gynecologic surgery experience and current medical licensure who are actively involved in the instruction and supervision of fellows during the time of accredited education.*
- The program has the resources, including adequate clinical facilities, laboratory research facilities, and appropriately trained faculty and staff, to provide research experience.*

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

- ☐ ***Completion of either a formal abdominal organ (kidney, liver, intestine, or pancreas) transplant fellowship or clinical experience pathway as outlined in OPTN membership requirements.***

***If this individual proposed is not already the primary surgeon of a kidney, liver, intestine, or pancreas program, a corresponding application will be required to document how the surgeon fulfills requirements.***

- ☐ ***The surgeon must have completed at least 2 uterus transplants as primary surgeon or co-surgeon. This includes completion of pre-operative assessments and post-operative care for a minimum of 90 days after surgery.***

***Provide a log of these procedures that includes the date of the transplant, the role of the surgeon in the transplant, and the medical record number or other unique identified 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 surgeon must have completed at least 15 radical hysterectomies within the last five years as the primary surgeon.

***Provide a log of these procedures 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 identified 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

***Provide a list of these individuals with the application to show proof of collaboration.***

Note: 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.

**4E: Additional Primary Surgeon Requirements for External Male Genitalia, Other Genitourinary Organ, Vascularized Gland, Lower Limb, Musculoskeletal Composite Graft Segment, and Spleen 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, uterus, or abdominal wall transplant programs. The VCA transplant program must specify the types of body part(s) it will transplant in the application.

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

- ☐ External Male Genitalia
- ☐ Other Genitourinary Organ
- ☐ Vascularized Gland
- ☐ Lower Limb
- ☐ Musculoskeletal Composite Graft Segment
- ☐ Spleen

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

- ☐ 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.**

- ☐ 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:**

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- **Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that:**
  - o The surgeon obtains 60 hours of Category I continuing medical education (CME) credits.
  - o The surgeon performs a self-assessment that is relevant to the individual's practice every three years, with a score of 75% or higher. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program.
  - o The transplant hospital document completion of this continuing education.
- **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, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.*
  - o Any other matters judged appropriate.*
- 3. *The surgeon must have observed at least 2 multi-organ procurements.  
Provide a log of these observations that includes the date of procurement and Donor ID.*
- 4. *Provide proof that the surgeon has performed the pre-operative evaluation of at least 3 potential VCA transplant patients.  
Provide a log of these procedures that includes the dates of procedures, the role of the surgeon, and the medical record number, or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained.*
- 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.  
Provide documentation that the team has demonstrated detailed planning that is specific for the type of VCA transplant the program will perform.*
- 7. *This team must include a team member that has microvascular experience such as replantation, revascularization, free tissue transfer, and major flap surgery.  
Provide a log with at least two of these procedures that includes the dates of procedures, the role of the surgeon, and the medical record number, or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained.*
- 8. *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 2 through 7 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 Part 2: Certificate of Assessment):

Name	NPI # (optional)
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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**)

- ☐ The individual 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: \_\_\_\_\_

- ☐ The individual fulfills the OPTN requirements for a primary transplant surgeon or primary transplant physician at a designated transplant program.

List the program the surgeon or physician *can satisfy* primary personnel requirements for:

\_\_\_\_\_

**Note:** If the individual does not currently serve as a primary surgeon or primary physician, a transplant program application will be required to document how the surgeon or physician fulfills requirements.

- ☐ The individual 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 OPTN membership requirements.  
**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:

- ***Be ineligible for American board certification. Provide an explanation why the individual is ineligible:***

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- ***Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that:***
  - o *The physician obtains 60 hours of Category I continuing medical education (CME) credits.*
  - o *The physician performs a self-assessment that is relevant to the individual's practice every three years, with a score of 75% or higher. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program.*
  - o *The transplant hospital document completion of this continuing education.*
- ***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. and familiarity with and experience in adhering to OPTN obligations and compliance protocols.*
  - o *Any other matters judged appropriate.*

## Part 7: Primary Obstetrician-Gynecologist Requirements (for Uterus Transplant Programs only)

1. Name of Proposed Primary Obstetrician-Gynecologist (as indicated in Part 2: Certificate of Assessment):

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Name

NPI # (optional)

2. Check to attest to each of the following. Provide documentation where applicable:

- ☐ The obstetrician-gynecologist 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. **Provide a copy of the obstetrician-gynecologist's medical license and resume/CV/documentation of education to show proof of this requirement.**
- ☐ The obstetrician-gynecologist has 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 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.**

3. Certification. Check one and provide corresponding documentation:

- ☐ The obstetrician-gynecologist 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. **Provide a copy of the obstetrician-gynecologist's current board certification.**
- ☐ The obstetrician-gynecologist is without certification 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.  
If this option is selected:
- **The obstetrician-gynecologist must be ineligible for American board certification. Provide an explanation why the individual is ineligible:**  
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  - **Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that:**
    - o **The obstetrician-gynecologist obtains 60 hours of Category I continuing medical education (CME) credits.**



- o The obstetrician-gynecologist performs a self-assessment that is relevant to the individual's practice every three years, with a score of 75% or higher. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program.*
  - o The transplant hospital document completion of this continuing education.*
- *Provide at least two letters of recommendation from directors of obstetrics and gynecology departments 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 obstetrician-gynecologist.*
  - o The individual's personal integrity and honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.*
  - o Any other matters judged appropriate.*

## **Part 8: VCA Transplant Program that Perform Living Donor VCA Recovery (for Uterus Transplant Programs only)**

A uterus recovery hospital is a designated uterus transplant program that performs the surgery to recover uteri for transplantation from living donors.

***For questions 1 through 3, check to attest that the program has adequate resources in place for living donor uterus recovery:***

### **1. Protocols and Resources for Evaluations**

- ☐ The uterus recovery hospital has protocols and resources in place for performing living donor evaluations.

### **2. Living Donor Medical Evaluation**

- ☐ The uterus recovery hospital has the clinical resources available to assess the medical condition of and specific risks to the living donor.

### **3. Living Donor Psychological Evaluation**

- ☐ The uterus recovery hospital has the clinical resources to perform a psychosocial evaluation of the living donor.

### **4. 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.

**Name of Independent Living Donor Advocate (ILDA):** \_\_\_\_\_

## Part 8A: Primary Living Donor Uterus Surgeon

**Name of Proposed Living Donor Surgeon (as indicated in Part 2: Certificate of Assessment):**

Name	NPI # (optional)
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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.

***Provide a log of these procedures that includes the dates of procedures, 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.***

### **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 membership requirements; 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/20xx. 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 23.79 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 Information Collection Clearance Officer, 5600 Fishers Lane, Room 14N39, Rockville, Maryland, 20857 or [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov).