

OPTN Membership Application for Heart 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

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: _____

Heart Transplant Program Phone #: _____

Name of Person Completing Form: _____ Title: _____

Email Address of Person Completing Form: _____

Date Form is submitted to OPTN Contractor: _____

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.

- *Use the checkboxes to indicate if the individual is part of the main program and/or the pediatric component of the program. Multiple boxes may be checked.*
- *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.*

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:

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:** _

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:

- 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:

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 heart transplant program must identify at least one designated staff member to act as the transplant program director. The director must be a physician or surgeon who is a member of the transplant hospital staff.

Program Director(s) (list all):

Name	Credentials
Name	Credentials
Name	Credentials
Name	Credentials

Part 5: Primary Heart Transplant Surgeon Requirements

1. Name of applicant (as indicated in Part 2: Certificate of Assessment):

Name	NPI # (optional)
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- The applicant is being proposed as the Primary Heart Transplant Surgeon*
- The applicant is being proposed as the Primary Pediatric Heart Transplant Surgeon*

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 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 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. Certification. Check one and provide corresponding documentation:

- The surgeon is **currently certified** by the American Board of Thoracic Surgery or currently certified in thoracic surgery by 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 Thoracic Surgery. 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 24-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** by the American Board of Thoracic Surgery, current certification in thoracic surgery by the Royal College of Physicians and Surgeons of Canada **or pending certification** by the American Board of Thoracic Surgery.
*If this option is selected:**

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

- ***Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that:***
 - ***The surgeon obtains 60 hours of Category I continuing medical education (CME) credits.***
 - ***The surgeon performs a self-assessment that is relevant to the surgeon’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:***
 - ***Why an exception is reasonable.***
 - ***The surgeon’s overall qualifications to act as a primary heart transplant surgeon.***
 - ***The surgeon’s personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.***
 - ***Any other matters judged appropriate.***

4. Summarize the surgeon’s training and experience in transplant:

Training and Experience	Date (MM/DD/YY)		Transplant Hospital	Program Director
	Start	End		
Residency				
Fellowship				
Experience Post Fellowship				

5. Which of the following pathways is the proposed primary surgeon applying (check one, and complete the corresponding pathway section below):

- The **formal cardiothoracic surgery residency pathway**, as described in *Section 5A: Cardiothoracic Surgery Residency Pathway* below.
- The **12-month heart transplant fellowship pathway**, as described in *Section 5B: Twelve-month Heart Transplant Fellowship Pathway* below.
- The **heart transplant program clinical experience pathway**, as described in *Section 5C: Clinical Experience Pathway* below.

5A. Cardiothoracic Surgery Residency Pathway

Surgeons can meet the training requirements for primary heart transplant surgeon by completing a cardiothoracic surgery residency if *all* of the following conditions are met:

1. *During the cardiothoracic surgery residency, the surgeon performed **at least 20** heart or heart/lung transplants as primary surgeon or first assistant.*

This experience must be documented on a log that includes date of transplant, role of the surgeon, medical record number or other unique identifier that can be verified by the OPTN, and the training program director's signature.

2. *During the residency the surgeon performed **at least 10** heart or heart/lung procurements as primary surgeon or first assistant under the supervision of a qualified heart transplant surgeon. These procurements must have been performed anytime during the surgeon's cardiothoracic surgery residency and the two years immediately following cardiothoracic surgery residency completion.*

This experience must be documented on a log that includes the date of procurement, Donor ID, and the training program director's signature.

3. *The surgeon has maintained a current working knowledge of all aspects of heart transplantation, defined as a direct involvement in heart transplant patient care within the last 2 years.*

Check to attest to the following

- The surgeon has experience performing the transplant operation.*
 - The surgeon has experience with donor selection.*
 - The surgeon has experience with use of mechanical circulatory assist devices.*
 - The surgeon has experience with recipient selection.*
 - The surgeon has experience with post-operative hemodynamic care.*
 - The surgeon has experience with postoperative immunosuppressive therapy.*
 - The surgeon has experience with outpatient follow-up.*
4. ***Check to attest to the following***
 - This training was completed at a hospital with a cardiothoracic surgery training program approved by the American Board of Thoracic Surgery or the Royal College of Physicians and Surgeons of Canada.*
 5. ***Provide the following letters with the application:***
 - A letter from the director of the training program verifying that the surgeon has met the above requirements and is qualified to direct a heart transplant program.
 - A letter of recommendation from the training program's primary surgeon and transplant program director outlining:
 - The surgeon's overall qualifications to act as primary transplant surgeon.

- The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations.
- Any other matters judged appropriate.

The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.

- A letter from the surgeon that details the training and experience they have gained in heart transplantation.

5B. Twelve-month Heart Transplant Fellowship Pathway

Surgeons can meet the training requirements for primary heart transplant surgeon by completing a 12-month heart transplant fellowship if the following conditions are met:

1. *The surgeon performed **at least 20** heart or heart/lung transplants as primary surgeon or first assistant during the 12-month heart transplant fellowship.*

This experience must be documented on a log that includes the date of transplant, role of the surgeon, medical record number or other unique identifier that can be verified by the OPTN, and the fellowship director's signature.

2. *The surgeon performed **at least 10** heart or heart/lung procurements as primary surgeon or first assistant under the supervision of a qualified heart transplant surgeon. These procurements must have been performed anytime during the surgeon's fellowship and the two years immediately following fellowship completion.*

This experience must be documented on a log that includes the date of procurement, Donor ID, and the training program director's signature.

3. *The surgeon has maintained a current working knowledge of all aspects of heart transplantation, defined as a direct involvement in heart transplant patient care within the last 2 years.*

Check to attest to the following

- The surgeon has experience performing the transplant operation.*
- The surgeon has experience with donor selection.*
- The surgeon has experience with use of mechanical circulatory assist devices.*
- The surgeon has experience with recipient selection.*
- The surgeon has experience with post-operative hemodynamic care.*
- The surgeon has experience with postoperative immunosuppressive therapy.*
- The surgeon has experience with outpatient follow-up.*

4. *Check to attest to the following*

- This training was completed at a hospital with a cardiothoracic surgery training program approved by the American Board of Thoracic Surgery or the Royal College of Physicians and Surgeons of Canada.*

5. *Provide the following letters with the application:*

- A letter from the director of the training program verifying that the surgeon has met the above requirements and is qualified to direct a heart transplant program.
- A letter of recommendation from the training program's primary surgeon and transplant program director outlining:
 - The surgeon's overall qualifications to act as primary transplant surgeon.

- The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations.
- Any other matters judged appropriate.

The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.

- A letter from the surgeon that details the training and experience they have gained in heart transplantation.

5C. Clinical Experience Pathway

Surgeons can meet the requirements for primary heart transplant surgeon through clinical experience gained post-fellowship if the following conditions are met:

1. *The surgeon has performed **20 or more** heart or heart/lung transplants as primary surgeon or first assistant at a designated heart transplant program. These transplants must have been completed over a 2 to 5-year period and include at least 15 of these procedures performed as the primary surgeon. Transplants performed during board qualifying surgical residency or fellowship do not count towards this experience.*

This experience must be documented on a log that includes the date of transplant, the role of the surgeon, and medical record number or other unique identifier that can be verified by the OPTN. This log should be signed by the program director, division chief, or department chair from the program where the experience was gained.

Note: Transplants performed during board qualifying surgical residency or fellowship do not count.

2. *The surgeon has performed **at least 10** heart or heart/lung procurements as primary surgeon or first assistant under the supervision of a qualified heart transplant surgeon.*

This experience must be documented on a log that includes the date of procurement and Donor ID.

3. *The surgeon has maintained a current working knowledge of all aspects of heart transplantation, defined as a direct involvement in heart transplant patient care within the last 2 years.*

Check to attest to the following

- The surgeon has experience performing the transplant operation.*
 - The surgeon has experience with donor selection.*
 - The surgeon has experience with use of mechanical circulatory assist devices.*
 - The surgeon has experience with recipient selection.*
 - The surgeon has experience with post-operative hemodynamic care.*
 - The surgeon has experience with postoperative immunosuppressive therapy.*
 - The surgeon has experience with outpatient follow-up.*
4. ***Provide the following letters with the application:***
 - A letter from the director of the program where the surgeon acquired transplant experience verifying that the surgeon has met the above requirements and is qualified to direct a heart transplant program.
 - A letter of recommendation from the primary surgeon and transplant program director at the transplant program last served by the surgeon outlining:
 - The surgeon's overall qualifications to act as primary transplant surgeon.

- The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations.
- Any other matters judged appropriate.

The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.

- A letter from the surgeon that details the training and experience they have gained in heart transplantation.

Part 6: Primary Heart Transplant Physician Requirements

1. Name of applicant (as indicated in Part 2: Certificate of Assessment):

Name	NPI # (optional)
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- The applicant is being proposed as the Primary Heart Transplant Physician*
- The applicant is being proposed as the Primary Pediatric Heart Transplant Physician*

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

- The physician has a 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 physician's medical license and resume/CV/documentation of education to show proof of this requirement.*
- The physician 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 physician's state license, board certification, training, and transplant continuing medical education, and that the physician is currently a member in good standing of the hospital's medical staff.*

3. Certification. Check one and provide corresponding documentation:

- The physician is currently certified in adult or pediatric cardiology or in advanced heart failure and transplant cardiology by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada.
Provide a copy of the physician's current board certification.*
- The physician is without certification in by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada.*
 - **The physician must be ineligible for American board certification. Provide an explanation why the physician is ineligible:**
 - **Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that:**
 - **The physician obtains 60 hours of Category I continuing medical education (CME) credits.**
 - **The physician performs a self-assessment that is relevant to the physician'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:*
 - *Why an exception is reasonable.*
 - *The physician’s overall qualifications to act as a primary heart transplant physician.*
 - *The physician’s personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.*
 - *Any other matters judged appropriate.*

4. Summarize the physician’s training and experience in transplant:

Training and Experience	Date (MM/DD/YY)		Transplant Hospital	Program Director
	Start	End		
Fellowship				
Experience Post Fellowship				

5. Which of the following pathways is the proposed primary physician applying? (check one, and complete the corresponding pathway section below):

- The **12-month transplant cardiology fellowship pathway**, as described in Section 5A: Twelve-month Transplant Cardiology Fellowship Pathway below.
- The **clinical experience pathway**, as described in Section 5B: Clinical Experience Pathway below.
- The **conditional approval pathway**, as described in Section 5C: Conditional Approval for Primary Transplant Physician below.

5A. Twelve-month Transplant Cardiology Fellowship Pathway

Physicians can meet the training requirements for primary heart transplant physician during a 12-month transplant cardiology fellowship if the following conditions are met:

1. *During the fellowship period, the physician was directly involved in the primary care of **at least 20** newly transplanted heart or heart/lung recipients.* This training will have been under the direct supervision of a qualified heart transplant physician and in conjunction with a heart transplant surgeon.

This experience must be documented on a log that includes the date of transplant, medical record number or other unique identifier that can be verified by the OPTN, and the signature of the director of the training program or the primary transplant physician.

2. *The physician has maintained a current working knowledge of heart transplantation, defined as direct involvement in heart transplant patient care within the last 2 years.*

Check to attest to the following

- The physician has experience with acute heart failure.*
- The physician has experience with chronic heart failure.*
- The physician has experience with donor selection.*
- The physician has experience with the use of mechanical circulatory support devices.*
- The physician has experience with recipient selection.*
- The physician has experience with pre- and post-operative hemodynamic care.*
- The physician has experience with post-operative immunosuppressive therapy.*
- The physician has experience with histological interpretation.*
- The physician has experience with grading myocardial biopsies for rejection.*
- The physician has experience with long-term outpatient follow-up.*

3. *The physician has observed **at least 3** heart procurements.* The physician must have observed the evaluation, donation process, and management of these donors.

This experience must be documented on a log that includes the date of procurement and Donor ID.

4. *The physician must have observed **at least 3** heart transplants.*

This experience must be documented on a log that includes the transplant date and medical record number or other unique identifier.

5. ***Check to attest to the following***

- This training was completed at a hospital with an American Board of Internal Medicine certified fellowship training program in adult cardiology, an American Board of Pediatrics certified fellowship training program in pediatric cardiology, or a cardiology training program approved by the Royal College of Physicians and Surgeons of Canada.*

6. ***Provide the following letters with the application:***

- A letter from the director of the training program and the supervising qualified heart transplant physician verifying that the physician has met the above requirements and is qualified to direct a heart transplant program.
- A letter of recommendation from the training program's primary physician and transplant program director outlining:
 - The physician's overall qualifications to act as primary transplant physician.
 - The physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations.
 - Any other matters judged appropriate.

The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.

- A letter from the physician that details the training and experience the physician has gained in heart transplantation.

5B. Clinical Experience Pathway

A physician can meet the requirements for primary heart transplant physician through acquired clinical experience if the following conditions are met.

1. *The physician has been directly involved in the primary care of **20 or more** newly transplanted heart or heart/lung recipients and continued to follow these recipients for a minimum of 3 months from transplant. This patient care must have been provided over a 2 to 5-year period on an active heart transplant service as the primary heart transplant physician or under the direct supervision of a qualified heart transplant physician and in conjunction with a heart transplant surgeon at a heart transplant program.*

This experience must be documented on a log that includes the date of transplant and medical record number or other unique identifier that can be verified by the OPTN. This recipient log should be signed by the director or the primary transplant physician at the transplant program where the physician gained this experience.

2. *The physician has maintained a current working knowledge of heart transplantation, defined as direct involvement in heart transplant patient care within the last 2 years.*

Check to attest to the following

- The physician has experience with acute heart failure.*
 - The physician has experience with chronic heart failure.*
 - The physician has experience with donor selection.*
 - The physician has experience with the use of mechanical circulatory support devices.*
 - The physician has experience with recipient selection.*
 - The physician has experience with pre- and post-operative hemodynamic care.*
 - The physician has experience with post-operative immunosuppressive therapy.*
 - The physician has experience with histological interpretation.*
 - The physician has experience with grading myocardial biopsies for rejection.*
 - The physician has experience with long-term outpatient follow-up.*
3. *The physician has observed **at least 3** heart procurements. The physician must have observed the evaluation, donation process, and management of these donors.*
This experience must be documented on a log that includes the date of procurement and Donor ID.
 4. *The physician has observed **at least 3** heart transplants.*
This experience must be documented on a log that includes the transplant date and medical record number or other unique identifier.

5. Provide the following letters with the application:

- A letter from the heart transplant physician or the heart transplant surgeon who has been directly involved with the physician at the transplant program verifying the physician's competence.
- A letter of recommendation from the program's primary physician and transplant program director at the transplant program last served by the physician outlining:
 - The physician's overall qualifications to act as primary transplant physician.
 - The physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations.
 - Any other matters judged appropriate.

The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.

- A letter from the physician that details the training and experience the physician has gained in heart transplantation.

5C. Conditional Approval for Primary Transplant Physician

If the primary heart transplant physician changes at an approved heart transplant program, a physician can serve as the primary heart transplant physician for a maximum of 12 months if the following conditions are met:

1. **Check to attest to the following**

- The physician has **12 months of experience** on an active heart transplant service as the primary heart transplant physician or under the direct supervision of a qualified heart transplant physician and in conjunction with a heart transplant surgeon at a designated heart transplant program. These 12 months of experience must be acquired within a 2-year period.*

2. *The physician has maintained a current working knowledge of heart transplantation, defined as direct involvement in heart transplant patient care within the last 2 years.*

Check to attest to the following

- The physician has experience with acute heart failure.*
- The physician has experience with chronic heart failure.*
- The physician has experience with donor selection.*
- The physician has experience with the use of mechanical circulatory support devices.*
- The physician has experience with recipient selection.*
- The physician has experience with pre- and post-operative hemodynamic care.*
- The physician has experience with post-operative immunosuppressive therapy.*
- The physician has experience with histological interpretation.*
- The physician has experience with grading myocardial biopsies for rejection.*
- The physician has experience with long-term outpatient follow-up.*

3. *The physician has been involved in the primary care of **10 or more** newly transplanted heart or heart/lung transplant recipients as the heart transplant physician or under the direct supervision of a qualified heart transplant physician or in conjunction with a heart transplant surgeon at a designated heart transplant program. The physician will have followed these patients for a minimum of 3 months from the time of transplant.*

This experience must be documented on a log that includes the date of transplant and medical record number or other unique identifier that can be verified by the OPTN. This recipient log should be signed by the program director or the primary transplant physician at the transplant program where the physician gained experience.

4. *The physician has observed **at least 3** heart procurements. The physician must have observed the evaluation, donation process, and management of these donors.*

This experience must be documented on a log that includes the date of procurement and Donor ID.

5. *The physician has observed **at least 3 heart transplants.**
This experience must be documented on a log that includes the transplant date and medical record number or unique identifier that can be verified by the OPTN.*

6. ***Provide documentation** that the program has established and documented a **consulting relationship** with counterparts at another heart transplant program.*

7. *The transplant program will **submit activity reports** to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress to meet the required involvement in the primary care of 20 or more heart transplant recipients, or that the program is making sufficient progress in recruiting a physician who meets all requirements for primary heart transplant physician by the end of the 12-month conditional approval period.*

8. ***Provide the following letters along with the application:***
 - A letter from the heart transplant physician or the heart transplant surgeon who has been directly involved with the physician at the transplant program verifying the physician's competence.
 - A letter of recommendation from the primary physician and director at the transplant program last served by the physician outlining:
 - The physician's overall qualifications to act as primary transplant physician.
 - The physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations.
 - Any other matters judged appropriate.The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
 - A letter from the physician that details the training and experience the physician has gained in heart transplantation.

Part 7: Pediatric Transplant Component

Heart Transplant Programs that Register Candidates Less than 18 Years Old

A designated heart transplant program that registers candidates less than 18 years old must have an approved pediatric component. To be approved for a pediatric component, the designated heart transplant program must identify a qualified primary pediatric heart transplant surgeon and a qualified primary pediatric heart transplant physician, as described below.

Instructions for Pediatric Component:

To propose a **primary pediatric heart surgeon**, complete section 7A of this application.

- If the surgeon is already the approved primary surgeon of the heart transplant program, complete numbers **1 and 3**.
- If the surgeon is **NOT** already the approved primary surgeon of the heart transplant program, complete numbers **1, 2, and 3**. To demonstrate that the proposed surgeon meets the OPTN requirements for both primary heart surgeon and primary pediatric heart surgeon, check the box in number 2 to identify the desired pathway and complete Part 5 of this application.

To propose a **primary pediatric heart physician**, complete section 7B of this application.

- If the physician is already the approved primary physician of the heart transplant program, complete numbers **1, 2, and 4**.
- If the physician is **NOT** already the approved primary physician of the heart transplant program, complete numbers **1-4**. To demonstrate that the proposed physician meets the OPTN requirements for both primary heart physician and primary pediatric heart physician, check the box in number 3 to identify the desired pathway and complete Part 6 of this application.

To apply for **conditional approval of a pediatric component**, complete section 7C of this application.

- For conditional approval, either the proposed primary surgeon or physician must be fully approved per OPTN requirements.
 - Select **Option A** if the program has a qualified primary pediatric heart **physician** who meets all of the requirements but the **surgeon** is seeking approval conditionally.
 - Select **Option B** if the program has a qualified primary pediatric heart **surgeon** who meets all of the requirements but the **physician** is seeking approval conditionally.

Part 7A: Primary Pediatric Heart Transplant Surgeon Requirements

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

Name	NPI # (optional)
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2. Which of the following pathways is the proposed primary pediatric surgeon applying (check one, and complete Part 5 of this application):

- The formal cardiothoracic surgery residency pathway, as described in Section 5A: Cardiothoracic Surgery Residency Pathway above.
- The 12-month heart transplant fellowship pathway, as described in Section 5B: Twelve-month Heart Transplant Fellowship Pathway above.
- The heart transplant program clinical experience pathway, as described in Section 5C: Clinical Experience Pathway above.

3. Pediatric-Specific Requirements

- a. The surgeon has performed **at least 8** heart transplants, as the primary surgeon or first assistant, in recipients less than 18 years old at the time of transplant. **At least 4** of these heart transplants must have been in recipients less than 6 years old or weighing less than 25 kilograms at the time of transplant. These transplants must have been performed during or after fellowship, or across both periods.

This experience must be documented on a log that includes the date of transplant, the recipient's date of birth, the recipient's weight at transplant if less than 25 kilograms, the role of the surgeon, and the medical record number or other unique identifier that can be verified by the OPTN.

- b. The surgeon has maintained a current working knowledge of pediatric heart transplantation, defined as a direct involvement in pediatric heart transplant patient care within the last 2 years.

Check to attest to the following

- The surgeon has experience performing the pediatric transplant operations.
- The surgeon has experience with donor selection.
- The surgeon has experience with the use of mechanical circulatory assist devices.
- The surgeon has experience with pediatric recipient selection.
- The surgeon has experience with post-operative hemodynamic care.
- The surgeon has experience with post-operative immunosuppressive therapy.
- The surgeon has experience with outpatient follow-up.

Part 7B: Primary Pediatric Heart Transplant Physician Requirements

1. **Name of Proposed Primary Pediatric Heart Transplant Physician (as indicated in Part 2: Certificate of Assessment):**

Name	NPI # (optional)
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2. **Certification. Check to attest and provide corresponding documentation:**

The physician is currently certified in pediatric cardiology by the American Board of Pediatrics. Provide a copy of the physician's current board certification.

3. **Which of the following pathways is the proposed primary pediatric physician applying (check one, and complete Part 6 of this application):**

The **12-month transplant cardiology fellowship pathway**, as described in *Section 6A: Twelve-month Transplant Cardiology Fellowship Pathway* above.

The **clinical experience pathway**, as described in *Section 6B: Clinical Experience Pathway* above.

The **conditional approval pathway**, as described in *Section 6C: Conditional Approval for Primary Transplant Physician* above.

4. **Pediatric-Specific Requirements**

• *The physician has current certification in pediatric cardiology by the American Board of Pediatrics. Provide a copy of the physician's current board certification.*

• *The physician has been directly involved in the primary care of **at least 8** heart transplant recipients less than 18 years old at the time of transplant. **At least 4** of these heart transplants must have been in recipients less than 6 years old or weighing less than 25 kilograms at the time of transplant. These transplants must have been performed during or after fellowship, or across both periods.*

This experience must be documented on a log that includes the date of transplant, the recipient's date of birth, the recipient's weight at transplant if less than 25 kilograms, and medical record number or other unique identifier that can be verified by the OPTN.

• *The physician has maintained a current working knowledge of pediatric heart transplantation, defined as a direct involvement in pediatric heart transplant patient care within the last 2 years.*

Check to attest to the following

The physician has experience with acute heart failure.

The physician has experience with chronic heart failure.

The physician has experience with donor selection.

- The physician has experience with the use of mechanical circulatory support devices.*
- The physician has experience with recipient selection.*
- The physician has experience with pre- and post-operative hemodynamic care.*
- The physician has experience with post-operative immunosuppressive therapy.*
- The physician has experience with histological interpretation.*
- The physician has experience with grading myocardial biopsies for rejection.*
- The physician has experience with long-term outpatient follow-up.*

Part 7C: Conditional Approval for a Pediatric Component

Instructions: Check Option A or Option B and complete the corresponding portions of the application. Provide supporting documentation where applicable.

- Option A.** The program has a qualified primary pediatric heart **physician** who meets all of the requirements described in **Part 7B: Primary Pediatric Heart Transplant Physician Requirements** above and a **surgeon** who meets all of the following requirements:

1. **Name of proposed primary pediatric heart transplant surgeon who meets conditional requirements:**

Name	NPI # (optional)
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2. The surgeon is the approved primary transplant surgeon for the heart transplant program or meets all of the requirements described in application *Part 3: Primary Heart Transplant Surgeon Requirements*, including completion of at least one of the following training or experience pathways:
 - The **formal cardiothoracic surgery residency pathway**, as described in application *Part 5, Section 5A: Cardiothoracic Surgery Residency Pathway*
 - The **12-month heart transplant fellowship pathway**, as described in application *Part 5, Section 5B: Twelve-month Heart Transplant Fellowship Pathway*
 - The **heart transplant program clinical experience pathway**, as described in application *Part 5, Section 5C: Clinical Experience Pathway*
If the surgeon is not the approved primary transplant surgeon of the heart program, complete Part 5 of this application.
3. *The surgeon has performed **at least 4** heart transplants, as the primary surgeon or first assistant, in recipients less than 18 years old at the time of transplant. **At least 1** of these heart transplants must have been in recipients less than 6 years old or weighing less than 25 kilograms at the time of transplant. These transplants must have been performed during or after fellowship, or across both periods.*
This experience must be documented on a log that includes the date of transplant, the recipient's date of birth, the recipient's weight at transplant if less than 25 kilograms, the role of the surgeon, and the medical record number or other unique identifier that can be verified by the OPTN.
4. *The surgeon maintained a current working knowledge of pediatric heart transplantation, defined as a direct involvement in pediatric heart transplant patient care within the last 2 years.*
Check to attest to the following

- The surgeon has experience performing the pediatric transplant operations.*
- The surgeon has experience with donor selection.*
- The surgeon has experience with the use of mechanical circulatory assist devices.*
- The surgeon has experience with pediatric recipient selection.*
- The surgeon has experience with post-operative hemodynamic care.*
- The surgeon has experience with post-operative immunosuppressive therapy.*
- The surgeon has experience with outpatient follow-up.*

- Option B.** The program has a qualified primary pediatric heart **surgeon** who meets all of the requirements described in **Part 7A: Primary Pediatric Heart Transplant Surgeon Requirements** above and a **physician** who meets all of the following requirements:

1. **Name of proposed primary pediatric heart transplant physician who meets conditional requirements:**

Name	NPI # (optional)
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2. The physician is the approved primary transplant physician for the heart program or meets all of the requirements described in *Part 6: Primary Heart Transplant Physician Requirements*, including completion of at least one of the following training or experience pathways:
- The **12-month transplant cardiology fellowship pathway**, as described in *Section 6A: Twelve-month Transplant Cardiology Fellowship Pathway* above.
 - The **clinical experience pathway**, as described in *Section 6B: Clinical Experience Pathway* above.
 - The **conditional approval pathway**, as described in *Section 6C: Conditional Approval for Primary Transplant Physician* above.
If the physician is not the approved primary transplant physician of the heart program, complete part 6 of this application.
3. The physician has current certification in pediatric cardiology by the American Board of Pediatrics.
Provide a copy of the physician's current board certification.
4. *The physician has been directly involved in the primary care of **at least 4** heart transplant recipients less than 18 years old at the time of transplant. **At least 1** of these heart transplants must have been in recipients less than 6 years old or weighing less than 25 kilograms at the time of transplant. These transplants must have been performed during or after fellowship, or across both periods. **This experience must be documented on a log that includes the date of transplant, the recipient's date of birth, the recipient's weight at transplant if less than 25 kilograms, and medical record number or other unique identifier that can be verified by the OPTN.***

5. *The physician has maintained a current working knowledge of pediatric heart transplantation, defined as a direct involvement in pediatric heart transplant patient care within the last 2 years.*

Check to attest to the following

- The physician has experience with acute heart failure.*
- The physician has experience with chronic heart failure.*
- The physician has experience with donor selection.*
- The physician has experience with the use of mechanical circulatory support devices.*
- The physician has experience with recipient selection.*
- The physician has experience with pre- and post-operative hemodynamic care.*
- The physician has experience with post-operative immunosuppressive therapy.*
- The physician has experience with histological interpretation.*
- The physician has experience with grading myocardial biopsies for rejection.*
- The physician has experience with long-term outpatient follow-up.*

A designated heart transplant program's conditional approval for a pediatric component is valid for a maximum of 24 months.

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 2/28/2029. 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 16.82 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 13N82, Rockville, Maryland, 20857 or paperwork@hrsa.gov.