

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.

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

OPTN Representative

Printed Name	Signature	Email Address
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Program Director

Printed Name	Signature	Email Address
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Program Director (if applicable)

Printed Name	Signature	Email Address
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Program Director (if applicable)

Printed Name	Signature	Email Address
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Program Director (if applicable)

Printed Name	Signature	Email Address
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Proposed Primary Surgeon

Printed Name	Signature	Email Address
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Proposed Primary Physician

Printed Name	Signature	Email Address
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Proposed Primary Pediatric Surgeon

Printed Name	Signature	Email Address
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Proposed Primary Pediatric Physician

Printed Name	Signature	Email Address
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Part 1: General Information

Name of Transplant Hospital: _____

OPTN Member Code (4 Letters): _____

Transplant Program Office Address

Street: _____ Ste: _____ Phone #: _____

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

Name of Person Completing Form: _____ Title: _____

Email Address of Person Completing Form: _____

Date Form is submitted to OPTN Contractor: _____

Check all that are applicable:

Pediatric Component

- Applying for Full Approval
- Applying for Conditional Approval

Part 2: 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.

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

Include the resume/CV of each individual listed.

Part 3: Primary Program Administrator

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

Name of Primary Program Administrator:

Credentials:

Title at Hospital:

Phone Number:

Email:

Part 4: Primary Data Coordinator

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

Name of Primary Data Coordinator:

Credentials:

Title at Hospital:

Phone Number:

Email:

Part 5: Primary Heart Transplant Surgeon Requirements

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

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

Yes No

- 2a. Does the surgeon have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction?

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

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

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

3. Certification. Check one and provide corresponding documentation:

- 3a. 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.

- 3b. 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.

- 3c. 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 individual is ineligible:**

- **Provide a plan for continuing education that is comparable to American board maintenance of certification; and**

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

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

Training and Experience	Approved Residency or Fellowship Program? Y/N	Date (MM/DD/YY)		Transplant Hospital	Program Director	# of Transplants as Primary		# of Transplants as 1st Assistant		# of Procurements as Primary or 1st Assistant	
		Start	End			Heart	Heart/Lung	Heart	Heart/Lung	Heart	Heart/Lung
Residency Training											
Fellowship Training											
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 5* Error: Reference source not found below.
- The **12-month heart transplant fellowship pathway**, as described in *Section 5* Error: Reference source not found below.
- The **heart transplant program clinical experience pathway**, as described in *Section 5* Error: Reference source not found 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 the log provided.*
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 the log provided.*
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 all that apply

- 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*

If a box is not checked, please provide an explanation:

4. **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 individual's overall qualifications to act as primary transplant surgeon,
 - the individual's personal integrity and honesty,
 - the individual's familiarity with and experience in adhering to OPTN obligations, and
 - 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 individual that details the training and experience they have gained in heart transplantation.

4B. 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 the log provided and signed by the fellowship director.
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 the log provided and signed by the fellowship director.
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 all that apply:***
 - 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****If a box is not checked, please provide an explanation:***

4. 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

- o the individual's overall qualifications to act as primary transplant surgeon,
- o the individual's personal integrity and honesty,
- o the individual's familiarity with and experience in adhering to OPTN obligations, and
- o 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 individual that details the training and experience they have gained in heart transplantation.

4C. 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 the log provided.

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 the log provided.

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 all that apply

- 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*

If a box is not checked, please provide an explanation:

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 individual's overall qualifications to act as primary transplant surgeon,
 - the individual's personal integrity and honesty,
 - the individual's familiarity with and experience in adhering to OPTN obligations, and
 - 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 individual that details the training and experience they have gained in heart transplantation.

Part 6: Primary Heart Transplant Physician Requirements

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

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

Yes No

- 2a. Does the physician have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction?

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

- 2b. Has the physician 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:

- 3a. 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.

- 3b. 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 individual is ineligible:**

- **Provide a plan for continuing education that is comparable to American board maintenance of certification**
- **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 heart transplant physician,**
 - o **the individual's personal integrity and honesty,**
 - o **the individual's familiarity with and experience in adhering to OPTN obligations and compliance protocols, and**
 - o **any other matters judged appropriate.**

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

Training and Experience	Date (MM/DD/YY)		Transplant Hospital	Program Director	# Heart Patients Followed			# Heart/Lung Patients Followed		
	Start	End			Pre	Peri	Post	Pre	Peri	Post
Fellowship Training										
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 5Error: Reference source not found below.
- The **clinical experience pathway**, as described in Section 5Error: Reference source not found below.
- The **conditional approval pathway**, as described in Section 5Error: Reference source not found below, if the primary heart transplant physician changes at an approved heart transplant program.

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 the log provided and signed by the training program director or the primary transplant physician at the transplant program.

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 all that apply

- 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*

If a box is not checked, please provide an explanation:

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 the log provided.

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

This experience must be documented on the log provided.

5. ***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:
 - o the individual's overall qualifications to act as primary transplant physician,
 - o the individual's personal integrity and honesty,
 - o The individual's familiarity with and experience in adhering to OPTN obligations, and
 - o 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 the log provided.

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 all that apply

- 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*

If a box is not checked, please provide an explanation:

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 the log provided.

4. *The physician has observed **at least 3** heart transplants.*

This experience must be documented on the log provided.

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 individual's overall qualifications to act as primary transplant physician,
 - the individual's personal integrity and honesty,
 - The individual's familiarity with and experience in adhering to OPTN obligations, and
 - 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. *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 all that apply

- 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*

If a box is not checked, please provide an explanation:

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 the log provided.

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 the log provided.

5. *The physician has observed **at least 3 heart transplants**.*
This experience must be documented on the log provided.

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

7. ***Provide documentation that 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 individual's overall qualifications to act as primary transplant physician,
 - the individual's personal integrity and honesty,
 - the individual's familiarity with and experience in adhering to OPTN obligations,
 - and 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.

Part 7A: Primary Pediatric Heart Transplant Surgeon Requirements

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

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

Yes No

- 2a. *Does the surgeon have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction?*

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

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

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

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

- 3a. *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.

- 3b. *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.

- 3c. *The surgeon is without American Board of Thoracic Surgery or current certification in thoracic surgery by the Royal College of Physicians and Surgeons of Canada.*

If this option is selected:

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

- ***Provide a plan for continuing education that is comparable to American board maintenance of certification; and***

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

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

Training and Experience	Approved Fellowship Program? Y/N	Date (MM/DD/YY)		Transplant Hospital	Program Director	# of Transplants as Primary		# of Transplants as 1st Assistant		# of Procurements as Primary or 1st Assistant	
		Start	End			Heart	Heart/Lung	Heart	Heart/Lung	Heart	Heart/Lung
Residency Training											
Fellowship Training											
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 5* Error: Reference source not found below.
- The **12-month heart transplant fellowship pathway**, as described in *Section 5* Error: Reference source not found below.
- The **heart transplant program clinical experience pathway**, as described in *Section 5* Error: Reference source not found 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 the log provided and signed by the training program director.

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 the log provided and signed by the training program director.

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 all that apply

- 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*

If a box is not checked, please provide an explanation:

4. ***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 individual's overall qualifications to act as primary transplant surgeon,
 - the individual's personal integrity and honesty,

- o the individual's familiarity with and experience in adhering to OPTN obligations, and
- o 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 individual 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 the log provided and signed by the fellowship director.

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 the log provided and signed by the fellowship director.

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 all that apply

- 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.*

If a box is not checked, please provide an explanation:

4. ***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 individual's overall qualifications to act as primary transplant surgeon,
 - the individual's personal integrity and honesty,
 - the individual's familiarity with and experience in adhering to OPTN obligations, and
 - 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 individual 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 the log provided.
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 the log provided.
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 all that apply

- 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.*

If a box is not checked, please provide an explanation:

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 program's primary surgeon and transplant program director outlining
 - the individual's overall qualifications to act as primary transplant surgeon,
 - the individual's personal integrity and honesty,
 - the individual's familiarity with and experience in adhering to OPTN obligations, and
 - 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 individual that details the training and experience they have gained in heart transplantation.

5. **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 the log provided.***

- 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 all that apply

- The surgeon has experience performing the pediatric 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 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*

If a box is not checked, please provide an explanation:

Part 7B: Primary Pediatric Heart Transplant Physician Requirements

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

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

Yes No

- 2a. Does the physician have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction?

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

- 2b. Has the physician 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:

- 3a. 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, of the Royal College of Physicians and Surgeons of Canada.

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

- 3b. The physician is without certification or has not achieved eligibility in adult or pediatric pulmonary medicine by the American Board of Internal Medicine, the American Board of Pediatrics, of 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:**

- **Provide a plan for continuing education that is comparable to American board maintenance of certification**
- **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 heart transplant physician,
 - o the individual's personal integrity and honesty,
 - o the individual's familiarity with and experience in adhering to OPTN obligations and compliance protocols, and

o any other matters judged appropriate.

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

Training and Experience	Date (MM/DD/YY)		Transplant Hospital	Program Director	# Heart Patients Followed			# Heart/Lung Patients Followed		
	Start	End			Pre	Peri	Post	Pre	Peri	Post
Fellowship Training										
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 5Error: Reference source not found* below.
- The **clinical experience pathway**, as described in *Section 5Error: Reference source not found* below.
- The **conditional approval pathway**, as described in *Section 5Error: Reference source not found* below, if the primary heart transplant physician changes at an approved heart transplant program.

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 the log provided and signed by the training program director or the primary transplant physician at the transplant program.

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 all that apply

- 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*

If a box is not checked, please provide an explanation:

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 the log provided.

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

This experience must be documented on the log provided.

5. ***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 individual's overall qualifications to act as primary transplant physician,
 - the individual's personal integrity and honesty,
 - The individual's familiarity with and experience in adhering to OPTN obligations, and
 - 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 the log provided.

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 all that apply

- 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.*

If a box is not checked, please provide an explanation:

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 the log provided.

4. *The physician has observed **at least 3** heart transplants.*

This experience must be documented on the log provided.

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 individual's overall qualifications to act as primary transplant physician,
 - the individual's personal integrity and honesty,
 - The individual's familiarity with and experience in adhering to OPTN obligations, and
 - 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 surgeon 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. *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 all that apply

- 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.*

If a box is not checked, please provide an explanation:

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 the log provided.
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 the log provided.
5. *The physician has observed **at least 3** heart transplants.*
This experience must be documented on the log provided.
6. ***Provide documentation*** that the program has established and documented a ***consulting relationship*** with counterparts at another heart transplant program.
7. ***Provide documentation*** that 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 your 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 individual's overall qualifications to act as primary transplant physician,
 - the individual's personal integrity and honesty,
 - the individual's familiarity with and experience in adhering to OPTN obligations,
 - and 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.

9. **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 the log provided.

- *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 all that apply:

- 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*

If a box is not checked, please provide an explanation:

Part 7C: Conditional Approval for a Pediatric Component

A designated heart transplant program can obtain conditional approval for a pediatric component if either of the following conditions is met:

Check one, 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 5C: Primary Pediatric Heart Transplant Physician Requirements* above and a **surgeon** who meets all of the following requirements:
- 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 3, Section 4A: Cardiothoracic Surgery Residency Pathway*
 - The 12-month heart transplant fellowship pathway, as described in application *Part 3, Section 4B: Twelve-month Heart Transplant Fellowship Pathway*
 - The heart transplant program clinical experience pathway, as described in application *Part 3, Section 4C: Clinical Experience Pathway*
 - *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 the log provided
 - *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 all that apply

- The surgeon has experience performing the pediatric 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 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*

If a box is not checked, please provide an explanation:

- Option B.** The program has a qualified primary pediatric heart surgeon who meets all of the requirements described in *Part 5B: Primary Pediatric Heart Transplant Surgeon Requirements* and a physician who meets all of the following requirements:
- The physician is the approved primary transplant physician for the heart program or meets all of the requirements described in *Part 4: Primary Heart Transplant Physician 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 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 the log provided
 - *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 all that apply
 - 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****If a box is not checked, please provide an explanation:***

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 Bylaw requirements for membership in the OPTN; and to monitor compliance of member organizations with OPTN Obligations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0915-0184 and it is valid until XX/XX/2023. This information collection is required to obtain or retain a benefit per 42 CFR §121.11(b)(2). All data collected will be subject to Privacy Act protection (Privacy Act System of Records #09-15-0055). Data collected by the private non-profit OPTN also are well protected by a number of the Contractor's security features. The Contractor's security system meets or exceeds the requirements as prescribed by OMB Circular A-130, Appendix III, Security of Federal Automated Information Systems, and the Departments Automated Information Systems Security Program Handbook. The public reporting burden for this collection of information is estimated to average 3 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 14N136B, Rockville, Maryland, 20857 or paperwork@hrsa.gov.