

OPTN Membership Application for Lung 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: _____

Lung 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.*

[illegible]

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

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 lung 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 Lung 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 Lung Transplant Surgeon
- ☐ The applicant is being proposed as the Primary Pediatric Lung 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 American Board of Thoracic Surgery certification 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:*

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- *Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that:*
 - o *The surgeon obtains 60 hours of Category I continuing medical education (CME) credits.*
 - o *The surgeon performs a self-assessment that is relevant to the individual's practice every three years, with a score of 75% or higher. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program.*
 - o *The transplant hospital document completion of this continuing education.*
 - *Provide at least 2 two letters of recommendation from directors of designated transplant programs not employed by the applying hospital that address:*
 - o *Why an exception is reasonable.*
 - o *The surgeon's overall qualifications to act as a primary lung transplant surgeon.*
 - o *The surgeon's personal integrity and honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.*
 - o *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 **cardiothoracic surgery residency pathway**, as described in *Section 5* below.
- ☐ The **12-month lung transplant fellowship pathway**, as described in *Section 5* below.
- ☐ The **lung transplant program clinical experience pathway**, as described in *Section 5* below.
- ☐ The **alternative pathway for predominantly pediatric programs**, as described in *Section 5* below.

5A. Cardiothoracic Surgery Residency Pathway

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

1. During the cardiothoracic surgery residency, the surgeon has performed **at least 15** lung or heart/lung transplants as primary surgeon or first assistant under the direct supervision of a qualified lung transplant surgeon and in conjunction with a lung transplant physician at a lung transplant program. **At least half** of these transplants must be lung procedures.

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

2. The surgeon has performed **at least 10** lung procurements as primary surgeon or first assistant under the supervision of a qualified lung 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 and Donor ID.

3. The surgeon must maintain a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years.

Check to attest to the following

- ☐ The surgeon has experience with acute lung failure.
- ☐ The surgeon has experience with chronic lung failure.
- ☐ The surgeon has experience with cardiopulmonary bypass.
- ☐ The surgeon has experience with donor selection.
- ☐ The surgeon has experience with recipient selection.
- ☐ The surgeon has experience with pre- and postoperative ventilator care.
- ☐ The surgeon has experience with postoperative immunosuppressive therapy.
- ☐ The surgeon has experience with histological interpretation and grading lung biopsies for rejection.
- ☐ The surgeon has experience with long-term outpatient follow-up.

4. **Check to attest to the following**

- ☐ This training was completed at a hospital with a cardiothoracic 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 lung transplant program.
- A letter of recommendation from the program's primary surgeon and transplant program director outlining:
 - o The surgeon's overall qualifications to act as primary transplant surgeon.
 - o The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
 - 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 surgeon that details the training and experience they have gained in lung transplantation.

5B. Twelve-month Lung Transplant Fellowship Pathway

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

1. *The surgeon has performed **at least 15** lung or heart/lung transplants under the direct supervision of a qualified lung transplant surgeon and in conjunction with a qualified lung transplant physician as primary surgeon or first assistant during the 12-month lung transplant fellowship. **At least half** of these transplants must be lung procedures.*

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

2. *The surgeon has performed **at least 10** lung procurements as primary surgeon or first assistant under the supervision of a qualified lung 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 and Donor ID.

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

Check to attest to the following

- ☐ *The surgeon has experience with acute lung failure.*
- ☐ *The surgeon has experience with chronic lung failure.*
- ☐ *The surgeon has experience with cardiopulmonary bypass.*
- ☐ *The surgeon has experience with donor selection.*
- ☐ *The surgeon has experience with recipient selection.*
- ☐ *The surgeon has experience with pre- and postoperative ventilator care.*
- ☐ *The surgeon has experience with postoperative immunosuppressive therapy.*
- ☐ *The surgeon has experience with histological interpretation and grading lung biopsies for rejection.*
- ☐ *The surgeon has experience with long-term outpatient follow-up.*

4. ***Check to attest to the following***

- ☐ *This training was completed at a hospital with a cardiothoracic 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 lung transplant program.
- A letter of recommendation from the program's primary surgeon and transplant program director outlining:
 - o The surgeon's overall qualifications to act as primary transplant surgeon.
 - o The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations.
 - 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 surgeon that details the training and experience they have gained in lung transplantation.

5C. Clinical Experience Pathway

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

1. *The surgeon has performed **15 or more** lung or heart/lung transplants over a 2 to 5-year period as primary surgeon or first assistant at a designated lung transplant program. **At least half** of these transplants must be lung procedures, and **at least 10** must be performed as the primary surgeon. The surgeon must also have been actively involved with cardiothoracic surgery.*

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

2. *The surgeon has performed **at least 10** lung procurements.*

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 lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years.*

Check to attest to the following

- ☐ *The surgeon has experience with acute lung failure.*
- ☐ *The surgeon has experience with chronic lung failure.*
- ☐ *The surgeon has experience with cardiopulmonary bypass.*
- ☐ *The surgeon has experience with donor selection.*
- ☐ *The surgeon has experience with recipient selection.*
- ☐ *The surgeon has experience with pre- and postoperative ventilator care.*
- ☐ *The surgeon has experience with postoperative immunosuppressive therapy.*
- ☐ *The surgeon has experience with histological interpretation and grading lung biopsies for rejection.*
- ☐ *The surgeon has experience with long-term outpatient follow-up.*

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

- A letter from the director of the program where the surgeon gained their experience verifying that the surgeon has met the above requirements and is qualified to direct a lung transplant program.
- A letter of recommendation from the primary surgeon and transplant program director of the program last served by outlining:
 - o The surgeon's overall qualifications to act as primary transplant surgeon.
 - o The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations.

- 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 surgeon that details the training and experience they have gained in lung transplantation.

5D. Alternative Pathway for Predominantly Pediatric Programs

If a surgeon does not meet the requirements for primary lung transplant surgeon through either the training or clinical experience pathways, hospitals that serve predominantly pediatric patients may petition the MPSC in writing to consider the surgeon for primary transplant surgeon if the program can demonstrate that the following conditions are met:

1. Provide an explanation why the proposed surgeon needs to utilize this pathway:

2. The surgeon's lung transplant training or experience must be equivalent to the **formal cardiothoracic surgery residency pathway**, as described in Section 5, the **12-month lung transplant fellowship pathway**, as described in Section 5, or the **lung transplant program clinical experience pathway**, as described in Section 5 above.

Provide documentation that supports equivalent training and experience, such as a log that includes the date of transplant and/or procurement, role of the surgeon, and medical record number or other unique identifier that can be verified by the OPTN.

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

Check to attest to the following

- ☐ The surgeon has experience with acute lung failure.
- ☐ The surgeon has experience with chronic lung failure.
- ☐ The surgeon has experience with cardiopulmonary bypass.
- ☐ The surgeon has experience with donor selection.
- ☐ The surgeon has experience with recipient selection.
- ☐ The surgeon has experience with pre- and postoperative ventilator care.
- ☐ The surgeon has experience with postoperative immunosuppressive therapy.
- ☐ The surgeon has experience with histological interpretation and grading lung biopsies for rejection.
- ☐ The surgeon has experience with long-term outpatient follow-up.

4. Provide the following letter with the application:

A letter of recommendation from the primary surgeon and transplant program director of the fellowship training program or the transplant program last served by the surgeon outlining:

- o The surgeon's overall qualifications to act as primary transplant surgeon.
- o The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations.
- 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.

5. If this pathway is selected, the OPTN contractor will contact the program to schedule an informal discussion with the MPSC.

Part 6: Primary Lung 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 Lung Transplant Physician
- ☐ The applicant is being proposed as the Primary Pediatric Lung Transplant Physician

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

- ☐ The physician 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 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 pulmonary medicine 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.
- ☐ 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. This plan must at least require that:**
 - o **The physician obtains 60 hours of Category I continuing medical education (CME) credits.**

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

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 pulmonary fellowship pathway**, as described in Section 5Name of applicant (as indicated in Part 2: Certificate of Assessment): below.
- ☐ The **clinical experience pathway**, as described in Section 5 below.
- ☐ The **alternative pathway for predominantly pediatric programs**, as described in Section 5 below.
- ☐ The **conditional approval pathway**, as described in Section 5 below.

5A. Twelve-month Transplant Pulmonary Fellowship Pathway

Physicians can meet the training requirements for primary lung transplant physician during a 12-month transplant pulmonary fellowship if *all* of the following conditions are met:

1. *The physician was directly involved in the primary and follow-up care of **at least 15** newly transplanted lung or heart/lung recipients. This training will have been under the direct supervision of a qualified lung transplant physician and in conjunction with a lung transplant surgeon. **At least half** of these patients must be single or double-lung transplant recipients. **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 transplant program's primary transplant physician.***

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

Check to attest to the following

- ☐ *The physician has experience with acute lung failure.*
- ☐ *The physician has experience with chronic lung failure.*
- ☐ *The physician has experience with cardiopulmonary bypass.*
- ☐ *The physician has experience with donor selection.*
- ☐ *The physician has experience with recipient selection.*
- ☐ *The physician has experience with pre- and postoperative ventilator care.*
- ☐ *The physician has experience with postoperative immunosuppressive therapy.*
- ☐ *The physician has experience with histological interpretation and grading lung biopsies for rejection.*
- ☐ *The physician has experience with long-term outpatient follow-up.*

3. *The physician has observed **at least 3** lung or heart/lung 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** lung transplants.*

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

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 pulmonary medicine, an American Board of Pediatrics-certified fellowship training program in pediatric medicine, or a pulmonary*

medicine 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 verifying that the physician has met the above requirements and is qualified to direct a lung 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 they have gained in lung transplantation.

5B. Clinical Experience Pathway

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

1. *The physician has been directly involved in the primary care of **15 or more** newly transplanted lung or heart/lung recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. **At least half** of these transplants must be lung transplants. This patient care must have been provided over a 2 to 5-year period at a designated lung transplant program. This care must have been provided as the lung transplant physician or directly supervised by a qualified lung transplant physician along with a lung transplant surgeon.*

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

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

Check to attest to the following

- ☐ *The physician has experience with acute lung failure.*
 - ☐ *The physician has experience with chronic lung failure.*
 - ☐ *The physician has experience with cardiopulmonary bypass.*
 - ☐ *The physician has experience with donor selection.*
 - ☐ *The physician has experience with recipient selection.*
 - ☐ *The physician has experience with pre- and postoperative ventilator care.*
 - ☐ *The physician has experience with postoperative immunosuppressive therapy.*
 - ☐ *The physician has experience with histological interpretation and grading lung biopsies for rejection.*
 - ☐ *The physician has experience with long-term outpatient follow-up.*
3. *The physician has observed **at least 3** lung or heart/lung 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** lung transplants.*
This experience must be documented on a log that includes transplant date and medical record number or other unique identifier that can be verified by the OPTN.

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

- A letter from the lung transplant physician or surgeon of the training program who has been directly involved with the physician documenting the physician's competence.
- A letter of recommendation from the program's primary physician and transplant program director at the transplant program last served outlining:
 - o The physician's overall qualifications to act as primary transplant physician.
 - o The physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations.
 - 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 they have gained in lung transplantation.

5C. Alternative Pathway for Predominantly Pediatric Programs

If a physician does not meet the requirements for primary physician through any of the transplant fellowship or clinical experience pathways as described above, hospitals that serve predominantly pediatric patients may petition the MPSC in writing to consider the physician for primary transplant physician if the program can demonstrate that the following conditions are met:

1. ***Provide an explanation why the proposed physician needs to utilize this pathway:***

2. That the physician's lung transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in the **12-month transplant pulmonary fellowship pathway**, as described in Section 5Name of applicant (as indicated in Part 2: Certificate of Assessment): or the **clinical experience pathway**, as described in Section 5 above.

Provide documentation that supports equivalent training and experience, such as a log that includes the date of transplant and/or procurement, role of the surgeon, and medical record number or other unique identifier that can be verified by the OPTN.

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

Check to attest to the following

- ☐ *The physician has experience with acute lung failure.*
☐ *The physician has experience with chronic lung failure.*
☐ *The physician has experience with cardiopulmonary bypass.*
☐ *The physician has experience with donor selection.*
☐ *The physician has experience with recipient selection.*
☐ *The physician has experience with pre- and postoperative ventilator care.*
☐ *The physician has experience with postoperative immunosuppressive therapy.*
☐ *The physician has experience with histological interpretation and grading lung biopsies for rejection.*
☐ *The physician has experience with long-term outpatient follow-up.*

4. ***Provide letter(s) of recommendation*** from the primary physician and transplant program director of the fellowship training program or transplant program last served by the physician outlining:

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

5. If this pathway is selected, the OPTN contractor will contact the program to schedule an informal discussion with the MPSC.

5D. Conditional Approval for Primary Transplant Physician

If the primary lung transplant physician changes at an approved lung transplant program, a physician can serve as the primary lung 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 lung transplant service as the primary lung transplant physician or under the direct supervision of a qualified lung transplant physician and in conjunction with a lung transplant surgeon at a designated lung transplant program. These 12 months of experience must be acquired within a 2-year period.

- 2. The physician has been involved in the primary care of **8 or more** newly transplanted lung or heart/lung transplant recipients as the lung transplant physician or under the direct supervision of a qualified lung transplant physician and in conjunction with a lung transplant surgeon. **At least half** of these patients must be lung transplant recipients.

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.

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

Check to attest to the following

- ☐ The physician has experience with acute lung failure.
- ☐ The physician has experience with chronic lung failure.
- ☐ The physician has experience with cardiopulmonary bypass.
- ☐ The physician has experience with donor selection.
- ☐ The physician has experience with recipient selection.
- ☐ The physician has experience with pre- and postoperative ventilator care.
- ☐ The physician has experience with postoperative immunosuppressive therapy.
- ☐ The physician has experience with histological interpretation and grading lung biopsies for rejection.
- ☐ The physician has experience with long-term outpatient follow-up.

- 4. The physician has observed **at least 3** lung or heart/lung 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** lung transplants.*
This experience must be documented on a log that includes transplant date and medical record number or other unique identifier that can be verified by the OPTN.
6. ***Provide documentation*** that supports that the program has established and documented a ***consulting relationship*** with counterparts at another lung 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 in meeting the required involvement in the primary care of 20 or more lung transplant recipients, or that the program is making sufficient progress in recruiting a physician who will be on site and approved by the MPSC to assume the role of Primary Physician by the end of the 12-month conditional approval period.
8. ***Provide the following letters with the application:***
 - A letter from the supervising lung transplant physician or surgeon at the training program documenting the physician's competence.
 - 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 the individual's 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 lung transplantation.

Part 7: Pediatric Transplant Component

Lung Transplant Programs that Register Candidates Less than 18 Years Old

A designated lung 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 lung transplant program must identify a qualified primary pediatric lung transplant surgeon and a qualified primary pediatric lung transplant physician, as described below.

Instructions for Pediatric Component:

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

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

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

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

Part 7A: Primary Pediatric Lung Transplant Surgeon Requirements

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

Name	NPI # (optional)

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

- ☐ The **cardiothoracic surgery residency pathway**, as described in *Section 5* above.
- ☐ The **12-month lung transplant fellowship pathway**, as described in *Section 5* above.
- ☐ The **lung transplant program clinical experience pathway**, as described in *Section 5* above.
- ☐ The **alternative pathway for predominantly pediatric programs**, as described in *Section 5* above.

Part 7B: Primary Pediatric Lung Transplant Physician Requirements

1. Name of Proposed Primary Pediatric Lung Transplant Physician (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 physician applying (check one, and complete Part 6 of this application):

- ☐ The **12-month transplant pulmonary fellowship pathway**, as described in Section 5Name of applicant (as indicated in Part 2: Certificate of Assessment): above.
- ☐ The **clinical experience pathway**, as described in *Section 5* above.
- ☐ The **alternative pathway for predominantly pediatric programs**, as described in *Section 5* above.
- ☐ The **conditional approval pathway**, as described in *Section 5* above.

PUBLIC BURDEN STATEMENT

The private, non-profit Organ Procurement and Transplantation Network (OPTN) collects this information in order to perform the following OPTN functions: to assess whether applicants meet OPTN membership requirements; and to monitor compliance of member organizations with OPTN Obligations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0915-0184 and it is valid until xx/xx/20xx. This information collection is required to obtain or retain a benefit per 42 CFR §121.11(b)(2). All data collected will be subject to Privacy Act protection (Privacy Act System of Records #09-15-0055). Data collected by the private non-profit OPTN also are well protected by a number of the Contractor's security features. The Contractor's security system meets or exceeds the requirements as prescribed by OMB Circular A-130, Appendix III, Security of Federal Automated Information Systems, and the Departments Automated Information Systems Security Program Handbook. The public reporting burden for this collection of information is estimated to average 5.79 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Information Collection Clearance Officer, 5600 Fishers Lane, Room 14N39, Rockville, Maryland, 20857 or paperwork@hrsa.gov.