# 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.

If you have any questions, please call the UNOS Membership Team at 833-577-9469 or email <a href="MembershipRequests@unos.org">MembershipRequests@unos.org</a>.

	OPTN Representative	
Printed Name	Signature	Email Address
	Position	
Printed Name	Signature	Email Address
	Position	
Printed Name	Signature	Email Address
	Position	
Printed Name		Email Address

#### Department of Health and Human Services Health Resources and Services Administration

Printed Name Signature Email Address

Position \_\_\_\_\_

Printed Name Signature Email Address

OMB No. 0915-0184

Expiration Date: 08/31/2023

Department of Health and Human Services Health Resources and Services Administration OMB No. 0915-0184

Expiration Date: 08/31/2023

# **Part 1: General Information**

Name of Transplant Hospital:						
OPTN Member Code (4 Let	ters):					
Transplant Hospital Addres	s (where transpla	ants occur)				
Street:		S	te: Pho	one #:		
City:	ST:	Zip:	Fax	#:		
Name of Person Completin	g Form:		Title	e:		
Email Address of Person Completing Form:						
Date Form is submitted to OPTN Contractor:						

# Part 2: 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.

Name of Program Director (list all):		Existing
	□	

Include the resume/CV of each new individual listed.

OMB No. 0915-0184

Expiration Date: 08/31/2023

# **Part 3: Primary Program Administrator**

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

Complete this section only if you are updating the Primary Program Administrator position for the program.

Name of Primary Program Administrator:

Credentials:

Title at Hospital:

Phone Number:

OMB No. 0915-0184

Expiration Date: 08/31/2023

# **Part 4: Primary Data Coordinator**

A primary data coordinator is the identified data lead for the transplant program.
Complete this section only if you are updating the Primary Data Coordinator position for the program.
Name of Primary Data Coordinator:
Credentials:
Title at Hospital:
Phone Number:
Email:

# **Part 5: Primary Lung Transplant Surgeon Requirements**

OMB No. 0915-0184

Expiration Date: 08/31/2023

	Name	NPI #
2.	Check yes or no for each of the following. Provide documen	tation where applicable:
es No	o	
	2a. Does the surgeon have an M.D., D.O., or equivalent de current license to practice medicine in the hospital's state or ju	-
	Provide a copy of the surgeon's resume/CV.	misuretion.
] 🗆 2	2b. Has the surgeon been accepted onto the hospital's medical hospital?	staff, and is practicing on site at thi
	Provide documentation from the hospital credentialing of surgeon's state license, board certification, training, are education, and that the surgeon is currently a member is medical staff.	nd transplant continuing medica
3.	Certification. Check one and provide corresponding docume	entation:
]	3a. The surgeon is currently certified by the American Board o	<u> </u>
]	3a. The surgeon is currently certified by the American Board of certified in thoracic surgery by the Royal College of Physicians <b>Provide a copy of the surgeon's current board certification.</b>	<u> </u>
]	certified in thoracic surgery by the Royal College of Physicians  Provide a copy of the surgeon's current board certification.  3b. The surgeon has just completed training and is pending conformation of Thoracic Surgery. Therefore, the surgeon is requesting conformation time to complete board certification, with the possibility	s and Surgeons of Canada.  Pertification by the American Board ditional approval for 24 months to
	certified in thoracic surgery by the Royal College of Physicians <b>Provide a copy of the surgeon's current board certification.</b> 3b. The surgeon has just completed training and is pending conformatic Surgery. Therefore, the surgeon is requesting conformation allow time to complete board certification, with the possibilit month period.	s and Surgeons of Canada.  Pertification by the American Board ditional approval for 24 months to by of renewal for one additional 24-
	Provide a copy of the surgeon's current board certification.  3b. The surgeon has just completed training and is pending conformation of Thoracic Surgery. Therefore, the surgeon is requesting conformation time to complete board certification, with the possibility month period.  Provide documentation supporting that training has been conformation.	s and Surgeons of Canada.  ertification by the American Board ditional approval for 24 months to y of renewal for one additional 24-
	certified in thoracic surgery by the Royal College of Physicians <b>Provide a copy of the surgeon's current board certification.</b> 3b. The surgeon has just completed training and is pending conformatic Surgery. Therefore, the surgeon is requesting conformation allow time to complete board certification, with the possibilit month period.	s and Surgeons of Canada.  ertification by the American Board ditional approval for 24 months to y of renewal for one additional 24-
	Provide a copy of the surgeon's current board certification.  3b. The surgeon has just completed training and is pending conference of Thoracic Surgery. Therefore, the surgeon is requesting conference of allow time to complete board certification, with the possibility month period.  Provide documentation supporting that training has been conference of pending, which must include the anticipated date of board of the surgeon is requesting conference of the surgeon is requested to the sur	s and Surgeons of Canada.  Pertification by the American Board ditional approval for 24 months to by of renewal for one additional 24-completed and certification is certification and where the surgeous certification or current

programs not employed by the applying hospital that address

Department of Health and Human Services Health Resources and Services Administration OMB No. 0915-0184 Expiration Date: 08/31/2023

- o why an exception is reasonable,
- o the individual's overall qualifications to act as a primary lung 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	Program?	Date (MM/DD/YY)		Transplant	Program	# of Lung /Heart-Lung	# of Lung
and Experience		Start	End	Hospital	Director	Transplants	Procurements
Residency							
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 <b>formal cardiothoracic surgery residency pathway</b> , as described in <i>Section 5</i> below.		
	The <b>12-month lung transplant fellowship pathway</b> , as described in <i>Section 5</i> below.		
	The <b>lung transplant program clinical experience pathway</b> , as described in <i>Section 5</i> 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:

- 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, 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
<u>last 2 years.</u>
Check all that apply
$\square$ The surgeon has experience with acute lung failure.
$\square$ The surgeon has experience with chronic lung failure.
$\square$ The surgeon has experience with cardiopulmonary bypass.
$\square$ The surgeon has experience with donor selection.
$\square$ The surgeon has experience with recipient selection.
$\square$ The surgeon has experience with pre- and postoperative ventilator care.
$\square$ The surgeon has experience with postoperative immunosuppressive therapy.
$\Box$ The surgeon has experience with histological interpretation and grading lung biopsies f
rejection.
$\square$ The surgeon has experience with long-term 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 lung transplant program.

- A letter of recommendation from the 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 compliance protocols, 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.

5B. Twelve-month Lung Transplant Fellowship Pathway

a 12-month lung transplant fellowship if the following conditions are met:

Surgeons can meet the training requirements for primary lung transplant surgeon by completing

OMB No. 0915-0184

Expiration Date: 08/31/2023

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, and the followship.

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, 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 <u>within the</u>
<u>last 2 years</u> .
Check all that apply
$\square$ The surgeon has experience with acute lung failure.
$\square$ The surgeon has experience with chronic lung failure.
$\square$ The surgeon has experience with cardiopulmonary bypass.
$\square$ The surgeon has experience with donor selection.
$\square$ The surgeon has experience with recipient selection.
$\square$ The surgeon has experience with pre- and postoperative ventilator care.
$\square$ The surgeon has experience with postoperative immunosuppressive therapy.
$\Box$ The surgeon has experience with histological interpretation and grading lung biopsies for
rejection.
$\square$ The surgeon has experience with long-term 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 lung transplant program.

- A letter of recommendation from the 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 compliance protocols, 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.

#### 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.

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 <u>within the</u>
	<u>last 2 years</u> .
	Check all that apply
	$\square$ The surgeon has experience with acute lung failure.
	$\square$ The surgeon has experience with chronic lung failure.
	$\square$ The surgeon has experience with cardiopulmonary bypass.
	$\square$ The surgeon has experience with donor selection.
	$\square$ The surgeon has experience with recipient selection.
	$\square$ The surgeon has experience with pre- and postoperative ventilator care.
	$\square$ The surgeon has experience with postoperative immunosuppressive therapy.
	$\square$ The surgeon has experience with histological interpretation and grading lung biopsies for
	rejection.
	$\square$ The surgeon has experience with long-term 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 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 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 compliance protocols, 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.

## 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:

OMB No. 0915-0184

Expiration Date: 08/31/2023

2.	The surgeon's lung transplant training or experience must be equivalent to the <b>formal cardiothoracic surgery residency pathway</b> , as described in <i>Section 5</i> , the <b>12-month lung transplant fellowship pathway</b> , as described in <i>Section 5</i> , or the <b>lung transplant program clinical experience pathway</b> , as described in <i>Section 5</i> above.  This experience must be documented on a log that includes the date of transplant and/or		
	date of procurement, the role of the surgeon, and the medical record number or other unique identifier.		
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 <u>within the</u>		
	last 2 years.		
	Check all that apply		
	☐ The surgeon has experience with acute lung failure.		
	$\Box$ The surgeon has experience with chronic lung failure.		
	☐ The surgeon has experience with cardiopulmonary bypass.		
	$\Box$ The surgeon has experience with donor selection.		
	$\Box$ The surgeon has experience with recipient selection.		
	$\Box$ The surgeon has experience with pre- and postoperative ventilator care.		
	$\Box$ The surgeon has experience with postoperative immunosuppressive therapy.		
	$\square$ The surgeon has experience with histological interpretation and grading lung biopsies		
	for rejection.		
	$\square$ The surgeon has experience with long-term outpatient follow-up.		
	If a box is not checked, please provide an explanation:		

4. Provide the following letters with the application:

Lung-15

- 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 individual's overall qualifications to act as primary transplant surgeon,
  - 0 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.

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**

OMB No. 0915-0184

Expiration Date: 08/31/2023

1.	Name of Proposed Primary Lung Transplant Physician (as indicated in Certificate of Assessment):				
	Name	NPI #			
2.	Check yes or no for each of the following. Provide docu	mentation where applicable:			
es No	)				
	2a. Does the physician have an M.D., D.O., or equivaler current license to practice medicine in the hospital's state <b>Provide a copy of the physician's resume/CV.</b>	· ·			
	2b. Has the physician been accepted onto the hospital's nthis hospital?	nedical staff, and is practicing on site at			
	Provide documentation from the hospital credentialing physician's state license, board certification, training education, and that the physician is currently a membrane medical staff.	g, and transplant continuing medical			
3.	Certification. Check one and provide corresponding doc	cumentation:			
	3a. The physician is currently certified in adult or pediate Board of Internal Medicine, the American Board of Pedia and Surgeons of Canada.				
	Provide a copy of the physician's current board certifica	tion.			
	<ul> <li>3b. The physician is without certification or has not a pulmonary medicine by the American Board of Inter Pediatrics, of the Royal College of Physicians and Surgeor</li> <li>The physician must be ineligible for American board why the individual is ineligible:</li> </ul>	rnal Medicine, the American Board of ns of Canada.			
	Provide a plan for continuing education that is compared to the continuing education that is continuing education the continuing education the continuing education that is continuing education the continuing education the continuing education the continuing education that is continuing education the continuing education that is continuing education the continuing education that is continuing education the continuing educ	parable to American board			
	<ul> <li>maintenance of certification</li> <li>Provide at least 2 two letters of recommendation from programs not employed by the applying hospital the owny an exception is reasonable,</li> </ul>				
	<ul> <li>the individual's overall qualifications to act as a</li> <li>the individual's personal integrity and honesty,</li> <li>the individual's familiarity with and experience</li> </ul>				
	compliance protocols, and o any other matters judged appropriate.				

OMB No. 0915-0184

Expiration Date: 08/31/2023

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

Training and	Date (MM/DD/YY)		Transplant Hospital	Program Director	# Lung Patients Followed			# Heart/Lung Patients Followed		
Experience	Start	End			Pre	Peri	Post	Pre	Peri	Post
Experience Post Fellowship										
Fellowship Training										

5.	Which of the following pathways is the proposed primary physician applying (check one, and complete the corresponding pathway section below):
	$\square$ The <b>12-month transplant pulmonary fellowship pathway</b> , as described in Section
	5Name of Proposed Primary Lung Transplant Physician (as indicated in Certificate of Assessment): below.
	$\Box$ The <b>clinical experience pathway</b> , as described in <i>Section 5</i> below.
	☐ The alternative pathway for predominantly pediatric programs, as described in
	Section 5 below.
	$\square$ The <b>conditional approval pathway</b> , as described in <i>Section 5</i> below, if the primary
	lung transplant physician changes at an approved lung transplant program.

#### 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:

OMB No. 0915-0184

Expiration Date: 08/31/2023

- 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, 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 <u>within the last 2 years</u>.

Check all that apply
$\square$ The physician has experience with acute lung failure.
$\square$ The physician has experience with chronic lung failure.
$\square$ The physician has experience with cardiopulmonary bypass.
$\square$ The physician has experience with donor selection.
$\square$ The physician has experience with recipient selection.
$\square$ The physician has experience with pre- and postoperative ventilator care.
$\square$ The physician has experience with postoperative immunosuppressive therapy.
$\square$ The physician has experience with histological interpretation and grading lung
biopsies for rejection.
$\square$ 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.
- 5. Provide the following letters with the application:

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

- 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:
  - o the individual's overall qualifications to act as primary transplant physician,
  - 0 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.

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.

#### 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.

OMB No. 0915-0184

Expiration Date: 08/31/2023

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 transplant 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.

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 <u>within the last 2 years</u>.

#### Check all that apply

Спеск ан тпат арргу
$\square$ The physician has experience with acute lung failure.
$\square$ The physician has experience with chronic lung failure.
$\square$ The physician has experience with cardiopulmonary bypass.
$\square$ The physician has experience with donor selection.
$\square$ The physician has experience with recipient selection.
$\square$ The physician has experience with pre- and postoperative ventilator care.
$\square$ The physician has experience with postoperative immunosuppressive therapy.
$\square$ The physician has experience with histological interpretation and grading lung
biopsies for rejection.
$\square$ 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 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.
- 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 verifying that the physician has met the above requirements and is qualified to direct a lung transplant program.
- A letter of recommendation from the program's primary physician and transplant program director at the program last served 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 compliance protocols, 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.

#### 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:

OMB No. 0915-0184

Expiration Date: 08/31/2023

That the physician's lung transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in the <b>12-month transplant pulmonary fellowship pathway</b> , as described in Section 5Name of Proposed Primary Lung Transplant Physician (as indicated in Certificate of Assessment): or the <b>clinical experience pathway</b> , as described in Section 5 above.
This experience must be documented on a log that includes the date of transplant and/or
procurement and the medical record number or other unique identifier.
The physician has maintained a current working knowledge of all aspects of lung
transplantation, defined as direct involvement in lung transplant patient care <u>within the last</u>
2 years. Check all that apply
☐ The physician has experience with acute lung failure.
☐ The physician has experience with acute 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.
If a box is not checked, please provide an explanation:

- 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 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 compliance protocols, 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.

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:

OMB No. 0915-0184

Expiration Date: 08/31/2023

- 1. 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 <u>must be acquired within a 2-year period</u>.
- 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.
- 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 all that apply ☐ 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. If a box is not checked, please provide an explanation:

- 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.

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

#### 7. Provide the following letters with the application:

- A letter from the supervising lung transplant physician or surgeon at 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
  - 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 compliance protocols, 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 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.

# Part 7A: Primary Pediatric Lung Transplant Surgeon Requirements

OMB No. 0915-0184

Expiration Date: 08/31/2023

	Name	NPI #
2.	Check yes or no for each of the following. Provide doc	umentation where applicable:
s No	0	
	2a. Does the surgeon have an M.D., D.O., or equivale current license to practice medicine in the hospital's state. Provide a copy of the surgeon's resume/CV.	•
	2b. Has the surgeon been accepted onto the hospital's me hospital?	edical staff, and is practicing on site at thi
	Provide documentation from the hospital credential surgeon's state license, board certification, trainin education, and that the surgeon is currently a memmedical staff.	g, and transplant continuing medica
3.	Certification. Check one and provide corresponding do	ocumentation:
	3a. The surgeon is currently certified by the American Be certified in thoracic surgery by the Royal College of Phys <b>Provide a copy of the surgeon's current board certifica</b>	sicians and Surgeons of Canada.
	3b. The surgeon has just completed training and is pend of Thoracic Surgery. Therefore, the surgeon is requestin allow time to complete board certification, with the pos	ling certification by the American Board g conditional approval for 24 months to
	month period.  Provide documentation supporting that training has b	een completed and certification is
	r rovide documentation supporting that training has b	•
	pending, which must include the anticipated date of bis in the process to be certified.	
		•

• Provide at least 2 two letters of recommendation from directors of designated transplant programs not employed by the applying hospital that address

OMB No. 0915-0184

Expiration Date: 08/31/2023

- o why an exception is reasonable,
- o the individual's overall qualifications to act as a primary lung 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	Approved Fellowship Program? Y/N	Date (MM/DD/YY)		Transplant	Program	# of Lung /Heart-Lung	# of Lung
and Experience		Start	End	Hospital	Director	Transplants	Procurements
Residency							
Fellowship Training							
Experience Post Fellowship							

5.	of the following pathways is the proposed primary surgeon applying (check one, and ete the corresponding pathway section below):
	The <b>formal cardiothoracic surgery residency pathway</b> , as described in <i>Section 5</i> below.
	The <b>12-month lung transplant fellowship pathway</b> , as described in <i>Section 5</i> below.
	The <b>lung transplant program clinical experience pathway</b> , as described in <i>Section 5</i> below.
	The <b>alternative pathway for predominantly pediatric programs</b> , as described in <i>Section</i> 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:

Services OMB No. 0915-0184 ninistration Expiration Date: 08/31/2023

- 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, 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 <u>within the</u>
	<u>last 2 years.</u> Check all that apply
	$\square$ The surgeon has experience with acute lung failure.
	$\square$ The surgeon has experience with chronic lung failure.
	$\square$ The surgeon has experience with cardiopulmonary bypass.
	$\square$ The surgeon has experience with donor selection.
	$\square$ The surgeon has experience with recipient selection?
	$\square$ The surgeon has experience with pre- and postoperative ventilator care.
	$\square$ The surgeon has experience with postoperative immunosuppressive therapy.
	$\square$ The surgeon has experience with histological interpretation and grading lung biopsies
	for rejection.
	$\square$ The surgeon has experience with long-term 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 lung transplant program.
- A letter of recommendation from the 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 compliance protocols, 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.

#### 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:

OMB No. 0915-0184

Expiration Date: 08/31/2023

- 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, 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 all that apply

$\Box$ The surgeon has experience with long-term outpatient If a box is not checked, please provide an explanation:	nt follow-up.
for rejection.	
$\square$ The surgeon has experience with histological interpre	tation and grading lung biopsie
$\square$ The surgeon has experience with postoperative immu	inosuppressive therapy.
$\square$ The surgeon has experience with pre- and postoperat	ive ventilator care.
$\hfill\square$ The surgeon has experience with recipient selection.	
$\square$ The surgeon has experience with donor selection.	
$\square$ The surgeon has experience with cardiopulmonary by	rpass.
$\square$ The surgeon has experience with chronic lung failure.	
$\square$ The surgeon has experience with acute lung failure.	
• • •	

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 lung transplant program.

- A letter of recommendation from the 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 compliance protocols, 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.

#### **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:

 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.

- 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 <u>within the last 2 years</u>.

#### Check all that apply

	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
fo	r rejection.
	The surgeon has experience with long-term outpatient follow-up.
If a bo	x is not checked, please provide an explanation:

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

- A letter from the director of 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 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 compliance protocols, 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.

#### 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:

OMB No. 0915-0184

Expiration Date: 08/31/2023

2.	The surgeon's lung transplant training or experience must be equivalent to the <b>formal</b> cardiothoracic surgery residency pathway, as described in <i>Section 5</i> , the <b>12-month lung</b> transplant fellowship pathway, as described in <i>Section 5</i> , or the lung transplant program clinical experience pathway, as described in <i>Section 5</i> above.
	This experience must be documented on a log that includes the date of transplant and/or procurement, the role of the surgeon, and the medical record number or other unique
	identifier.
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 <u>within the</u>
	<u>last 2 years</u> .
	Check all that apply
	$\square$ The surgeon has experience with acute lung failure.
	$\square$ The surgeon has experience with chronic lung failure.
	$\square$ The surgeon has experience with cardiopulmonary bypass.
	$\square$ The surgeon has experience with donor selection.
	$\square$ The surgeon has experience with recipient selection.
	$\square$ The surgeon has experience with pre- and postoperative ventilator care.
	$\square$ The surgeon has experience with postoperative immunosuppressive therapy.
	$\square$ The surgeon has experience with histological interpretation and grading lung biopsies
	for rejection.
	$\square$ The surgeon has experience with long-term outpatient follow-up.
	If a box is not checked, please provide an explanation:

4. Provide the following letters 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 individual's overall qualifications to act as primary transplant surgeon,
  - 0 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.

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 7B: Primary Pediatric Lung Transplant Physician Requirements

OMB No. 0915-0184

Expiration Date: 08/31/2023

	Name	NPI #
Chec	k yes or no for each of the following. Provide do	cumentation where applicable:
0		
curre	oes the physician have an M.D., D.O., or equivant license to practice medicine in the hospital's stacle a copy of the physician's resume/CV.	
2b. Ho	as the physician been accepted onto the hospital's ospital?	s medical staff, and is practicing on site a
physic educa	de documentation from the hospital credentia cian's state license, board certification, train ation, and that the physician is currently a me cal staff.	ing, and transplant continuing medica
Certi	fication. Check one and provide corresponding d	locumentation:
Boar	The physician is currently certified in adult or pedi d of Internal Medicine, the American Board of Pe Surgeons of Canada.	
	ide a copy of the physician's current board certifi	ication.
pulm Pedia • 7	The physician is without certification or has no nonary medicine by the American Board of Instatrics, of the Royal College of Physicians and Surge The physician must be ineligible for American boowhy the individual is ineligible:	ternal Medicine, the American Board o eons of Canada.
	Provide a plan for continuing education that is co	mparable to American board
	naintenance of certification Provide at least 2 two letters of recommendation	from directors of designated transplant
	programs not employed by the applying hospital	•
_	why an exception is reasonable,	
	the individual's overall qualifications to act a	
	the individual's personal integrity and honest the individual's familiarity with and experien	
	compliance protocols, and	ce in dunering to OF IN Obligations and
•	any other matters judged appropriate.	

OMB No. 0915-0184

Expiration Date: 08/31/2023

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

Training and	Date (MM/DD/YY)		Transplant Hospital	Program Director	# Lung Patients Followed			# Heart/Lung Patients Followed		
Experience	Start	End		J.: 3333.	Pre	Peri	Post	Pre	Peri	Post
Experience Post Fellowship										
Fellowship Training										

Which of the following pathways is the proposed primary physician applying (check one, and complete the corresponding pathway section below):
☐ The <b>12-month transplant pulmonary fellowship pathway</b> , as described in Section
5Name of Proposed Primary Lung Transplant Physician (as indicated in Certificate of
Assessment): below.
$\square$ The <b>clinical experience pathway</b> , as described in <i>Section 5</i> below.
☐ The alternative pathway for predominantly pediatric programs, as described in
Section 5 below.
☐ The <b>conditional approval pathway</b> , as described in <i>Section 5</i> below, if the primary
lung transplant physician changes at an approved lung transplant program.

### 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:

OMB No. 0915-0184

Expiration Date: 08/31/2023

- 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, 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 <u>within the last 2 years</u>.

## Check all that apply

$\square$ The physician has experience with acute lung failure.
$\square$ The physician has experience with chronic lung failure.
$\square$ The physician has experience with cardiopulmonary bypass.
$\square$ The physician has experience with donor selection.
$\square$ The physician has experience with recipient selection.
$\square$ The physician has experience with pre- and postoperative ventilator care.
$\square$ The physician has experience with postoperative immunosuppressive therapy.
$\square$ The physician has experience with histological interpretation and grading lung
biopsies for rejection.
$\square$ 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 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.**
- 5. 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:
  - 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 compliance protocols, 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 individual 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 transplant 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.

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 <u>within the last 2 years</u>.

## Check all that apply

check all that apply
$\square$ The physician has experience with acute lung failure.
$\square$ The physician has experience with chronic lung failure.
$\square$ The physician has experience with cardiopulmonary bypass.
$\square$ The physician has experience with donor selection.
$\square$ The physician has experience with recipient selection.
$\square$ The physician has experience with pre- and postoperative ventilator care.
$\square$ The physician has experience with postoperative immunosuppressive therapy.
$\square$ The physician has experience with histological interpretation and grading lung
biopsies for rejection.
$\square$ 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 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.
- 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 verifying that the physician has met the above requirements and is qualified to direct a lung transplant program.
- A letter of recommendation from the program's primary physician and transplant program director at the program last served 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 compliance protocols, 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 individual 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:

OMB No. 0915-0184

Expiration Date: 08/31/2023

•	That the physician's lung transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in the <b>12-month transplant pulmonary fellowship pathway</b> , as described in Section 5Name of Proposed Primary Lung Transplant Physician (as indicated in Certificate of Assessment): or the <b>clinical experience pathway</b> , as described in Section 5 above.
	This experience must be documented on a log that includes the date of transplant and/or
	procurement and the medical record number or other unique identifier.
	The physician has maintained a current working knowledge of all aspects of lung
	transplantation, defined as direct involvement in lung transplant patient care <u>within the last</u>
	2 years.
	Check all that apply
	$\square$ The physician has experience with acute lung failure.
	$\square$ The physician has experience with chronic lung failure.
	$\square$ The physician has experience with cardiopulmonary bypass.
	$\square$ The physician has experience with donor selection.
	$\square$ The physician has experience with recipient selection.
	$\square$ The physician has experience with pre- and postoperative ventilator care.
	$\square$ The physician has experience with postoperative immunosuppressive therapy.
	$\square$ The physician has experience with histological interpretation and grading lung
	biopsies for rejection.
	$\square$ The physician has experience with long-term outpatient follow-up.
	If a box is not checked, please provide an explanation:

- 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 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 compliance protocols, 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.

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:

OMB No. 0915-0184

Expiration Date: 08/31/2023

- 1. 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 <u>must be acquired within a 2-year period</u>.
- 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.
- 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 all that apply

check an that appry	
$\square$ The physician has experience with acute lung failure.	
$\square$ The physician has experience with chronic lung failure.	
$\square$ The physician has experience with cardiopulmonary bypass.	
$\square$ The physician has experience with donor selection.	
$\square$ The physician has experience with recipient selection.	
$\square$ The physician has experience with pre- and postoperative ventilator care.	
$\square$ The physician has experience with postoperative immunosuppressive therapy.	
$\square$ The physician has experience with histological interpretation and grading lung	
biopsies for rejection.	
$\square$ The physician has experience with long-term outpatient follow-up.	
f a box is not checked, please provide an explanation:	

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.

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

#### 7. Provide the following letters with the application:

- A letter from the supervising lung transplant physician or surgeon at 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
  - 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 compliance protocols, 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 lung transplantation.

#### **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 08/31/2023. 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 <a href="mailto:paperwork@hrsa.gov">paperwork@hrsa.gov</a>.

Department of Health and Human Services Health Resources and Services Administration OMB No. 0915-0184

Expiration Date: 08/31/2023