**OPTN Membership Application for** 

OMB No. 0915-0184

Expiration Date: 08/31/2023

### **CERTIFICATION**

**Kidney Transplant Programs** 

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

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

	от торгоостино	
Printed Name	Signature	Email Address
	Program Director	
Printed Name	Signature	Email Address
	Program Director (if applicable)	
Printed Name	Signature	Email Address
	Program Director (if applicable)	
Printed Name	Signature	Email Address
	Program Director (if applicable)	
Printed Name		Email Address

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### **Proposed Primary Surgeon**

Printed Name	Signature	Email Address
	<b>Proposed Primary Physician</b>	
Printed Name	Signature	Email Address
	<b>Proposed Primary Pediatric Surgeon</b>	
Printed Name	Signature	Email Address
	Proposed Primary Pediatric Physician	
Printed Name	Signature Proposed Open Living Donor Nephrectomies	Email Address Surgeon
Printed Name	Signature	Email Address
	Proposed Laparoscopic Living Donor Kidney S	Surgeon
Printed Name	Signature	Email Address

# Human Services OMB No. 0915-0184

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## **Part 1: General Information**

Name of Transplant Hospital:			
OPTN Member Code (4 Letters):			
Transplant Program Office Address			
Street:	Ste:	Phone #:	
City: ST:	Zip:	Fax #:	
Name of Person Completing Form:		Title:	
Email Address of Person Completing Form:			
Date Form is submitted to OPTN Contractor:			
Check all that are applicable:			
Pediatric Component			
☐ Applying for Full Approval			
☐ Applying for Conditional Approval			
☐ Applying for Living Donor Component			

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# Part 2: Program Director(s)

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

Name of Program Director(s) (list all):	New	Existing
	_ 🗆	
	_ 🗆	
	_ 🗆	
	_ 🗆	

Include the resume/CV of each individual listed.

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# **Part 3: Primary Program Administrator**

A primary program administrator is the identified administrative lead for the transplant program.
Name of Primary Program Administrator:
Credentials:
Title at Hospital:
Phone Number:
Email:

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# **Part 4: Primary Data Coordinator**

A primary data coordinator is the identified data lead for the transplant program.		
Name of Primary Data Coordinator:		
Credentials:		
Title at Hospital:		
Phone Number:		
Email:		

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

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	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 equivalent de	egree from another country, with a curren
	license to practice medicine in the hospital's state or juri	isdiction?
	Provide a copy of the surgeon's resume/CV.	
	2b. Has the surgeon been accepted onto the hospital's monospital?	edical staff, and is practicing on site at thi
	Provide documentation from the hospital credential surgeon's state license, board certification, training education, and that the surgeon is currently a member staff.	ng, and transplant continuing medica
3.	Certification. Check one and provide corresponding do	ocumentation:
	3a. The surgeon is currently certified by the American B Urology, the American Board of Osteopathic Surgery, o Surgeons of Canada.	
	Provide a copy of the surgeon's current board certifica	ation.
	3b. The surgeon has just completed training and is pen	
	of Urology. Therefore, the program is requesting condit surgeon time to complete board certification, with the 116-month period.	tional approval for 16 months to allow the
	Provide documentation supporting that training has b	een completed and certification is
	pending, which must include the anticipated date of b	•
	is in the process to be certified.	
	3c. The surgeon is without certification by the American Urology, the American Board of Osteopathic Surgery, o Surgeons of Canada or pending certification by the American this option is selected:	r the Royal College of Physicians and

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

- Provide at least 2 two letters of recommendation from directors of designated transplant programs not employed by the applying hospital that address
  - o why an exception is reasonable,
  - o the individual's overall qualifications to act as a primary kidney transplant surgeon,

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- o the individual's personal integrity and honesty,
- the individual's familiarity with and experience in adhering to OPTN obligations and compliance protocols, and
- o any other matters judged appropriate.
- 4. Summarize the surgeon's training and experience in transplant:

Training and	Approved Fellowship Program?	Date (MM/DD/YY)		Transplant	Program	# Kidney Transplants	# Kidney Transplants as 1st	# of Kidney Procurements as Primary or
Experience	Y/N	Start	End	Hospital	Director	as Primary	Assistant	1 <sup>st</sup> Assistant
Fellowship Training								
Experience Post Fellowship								

which of the following pathways is the proposed primary surgeon applying (check one, and complete the corresponding pathway section below):
<ul> <li>☐ The <b>fellowship pathway</b>, as described in <i>Section 5A: Formal 2-year Transplant Fellowship Pathway</i> below.</li> <li>☐ The <b>clinical experience pathway</b>, as described in <i>Section 5B: Clinical Experience Pathway</i> below.</li> </ul>
5A. Formal 2-year Transplant Fellowship Pathway
Surgeons can meet the training requirements for primary kidney transplant surgeon by completing a formal 2-year surgical transplant fellowship if the following conditions are met:

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1. The surgeon performed **at least 30** kidney transplants as the primary surgeon or first

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This experience must be documented on the log provided.

assistant during the 2-year fellowship period.

2. The surgeon performed **at least 15** kidney procurements as primary surgeon or first assistant. At least 10 of these procurements must be from deceased donors. These procurements must have been performed anytime during the surgeon's fellowship and the two years immediately following fellowship completion.

This experience must be documented on the log provided.

3.	The surgeon has maintained a current working knowledge of kidney transplantation, defined
	as direct involvement in kidney transplant patient care in the last 2 years.
	Check all that apply
	$\square$ The surgeon has experience with managing patients with end stage renal disease.
	$\square$ The surgeon has experience with the selection of appropriate recipients for
	transplantation.
	$\square$ The surgeon has experience with donor selection.
	$\ \square$ The surgeon has experience with histocompatibility and tissue typing.
	$\ \square$ The surgeon has experience with performing the transplant operation.
	$\ \square$ The surgeon has experience with immediate postoperative and continuing inpatient care.
	$\square$ The surgeon has experience with the use of immunosuppressive therapy including side
	effects of the drugs and complications of immunosuppression.
	$\square$ The surgeon has experience with differential diagnosis of renal dysfunction in the
	allograft recipient.
	$\ \square$ The surgeon has experience with histological interpretation of allograft biopsies.
	$\square$ The surgeon has experience with interpretation of ancillary tests for renal dysfunction.
	$\square$ The surgeon has experience with long term outpatient care.
	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 and chair of the department or hospital credentialing committee verifying that the surgeon has met the above requirements and is qualified to direct a kidney transplant program.
- A letter of recommendation from the fellowship training program's primary surgeon and transplant program director outlining
  - o the individual's overall qualifications to act as primary transplant surgeon,
  - o the individual's personal integrity and honesty,
  - 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.

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• A letter from the surgeon that details the training and experience the surgeon has gained in kidney transplantation.

### 5B. Clinical Experience Pathway

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

The surgeon has performed 45 or more kidney transplants over a 2 to 5-year period as primary surgeon, co-surgeon, or first assistant at a designated kidney transplant program.
 Of these 45 kidney transplants, 23 or more must have been performed as primary surgeon or co-surgeon. Each year of the surgeon's experience must be substantive and relevant and include pre-operative assessment of kidney transplant candidates, performance of transplants as primary surgeon or first assistant, and post-operative care of kidney recipients.

This experience must be documented on the log provided.

2. The surgeon has performed **at least 15** kidney procurements as primary surgeon, co-surgeon, or first assistant. Of these 15 kidney procurements, at least 8 must have been performed as primary surgeon or co-surgeon. At least 10 of these procurements must be from deceased donors.

3. The surgeon has maintained a current working knowledge of kidney transplantation, defined

as direct involvement in kidney transplant patient care in the last 2 years.
Check all that apply
$\square$ The surgeon has experience with managing patients with end stage renal disease.
$\square$ The surgeon has experience with the selection of appropriate recipients for
transplantation.
$\square$ The surgeon has experience with donor selection.
$\square$ The surgeon has experience with histocompatibility and tissue typing.
$\square$ The surgeon has experience with performing the transplant operation.
$\Box$ The surgeon has experience with immediate postoperative and continuing inpatient care.
$\Box$ The surgeon has experience with the use of immunosuppressive therapy including side
effects of the drugs and complications of immunosuppression.
$\square$ The surgeon has experience with differential diagnosis of renal dysfunction in the
allograft recipient.
$\Box$ The surgeon has experience with histological interpretation of allograft biopsies.

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

Department of Health and Human Services

- A letter from the director of the transplant program and chair of the department or hospital credentialing committee verifying that the surgeon has met the above qualifications and is qualified to direct a kidney transplant program
- A letter of recommendation from the primary surgeon and transplant program director at the transplant program last served by the surgeon outlining
  - o the individual's overall qualifications to act as primary transplant surgeon,
  - o the individual's personal integrity and honesty,
  - the individual's familiarity with and experience in adhering to OPTN obligations and compliance protocols, and

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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 the surgeon has gained in kidney transplantation.

# **Part 6: Primary Kidney Transplant Physician Requirements**

A designated kidney transplant program must have a primary physician who meets *all* the following requirements:

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1		ame of Proposed Primary Kidney Transplant Physician (as indicated in Certificate of sessment):
2	. Ch	eck yes or no for each of the following. Provide documentation where applicable:
res N	lo	
	cur	n. Does the physician have an M.D., D.O., or equivalent degree from another country, with a rent license to practice medicine in the hospital's state or jurisdiction? Evide a copy of the physician's resume/CV.
	☐ 2b.	Has the physician been accepted onto the hospital's medical staff, and is practicing on site as hospital?
	phy edu	vide documentation from the hospital credentialing committee that it has verified the visician's state license, board certification, training, and transplant continuing medical cation, and that the physician is currently a member in good standing of the hospital' dical staff.
3	. Ce	rtification. Check one and provide corresponding documentation:
	3a	. The physician is currently certified in nephrology by the American Board of Internal Medicine
		e American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada.  ovide a copy of the physician's current board certification.
	3b <i>M</i>	o. The physician is without certification in nephrology by the American Board of Interno edicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Inada.
	•	The physician must be ineligible for American board certification. Provide an explanation why the individual is ineligible:
	•	Provide a plan for continuing education that is comparable to American board maintenance of certification
	•	Provide at least 2 two letters of recommendation from directors of designated transplant programs not employed by the applying hospital that address  why an exception is reasonable,
		<ul> <li>the individual's overall qualifications to act as a primary kidney transplant physician,</li> </ul>

o the individual's personal integrity and honesty,

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- the individual's familiarity with and experience in adhering to OPTN obligations and compliance protocols, and
- o any other matters judged appropriate.
- 4. Summarize the physician's training and experience in transplant:

Training	Approved Fellowship Program? Y/N	Date (MM/DD/YY)				#Kidney Patients Followed		
and Experience		Start	End	Transplant Hospital	Program Director	Pre	Peri	Post
Fellowship Training								
Experience Post Fellowship								

complete the corresponding pathway section below):	
☐ The <b>transplant nephrology fellowship pathway</b> , as described in <i>Section 5A: Transplant Nephrology Fellowship Pathway</i> below.	
☐ The clinical experience pathway, as described in Section 5B: Clinical Experience Pathway	
below.	
☐ The <b>3 year pediatric nephrology fellowship pathway</b> , as described in <i>Section 5C: Three-year</i>	
Pediatric Nephrology Fellowship Pathway below.	
☐ The <b>12-month pediatric transplant nephrology fellowship pathway</b> , as described in <i>Section</i> 5D: Twelve-month Pediatric Transplant Nephrology Fellowship Pathway below.	
☐ The <b>combined pediatric nephrology training and experience pathway</b> , as described in	
Section 5E. Combined Pediatric Nephrology Training and Experience Pathway below.	
☐ The <b>conditional approval pathway</b> , as described in <i>Section 5F: Conditional Approval for</i>	
Primary Transplant Physician below, if the primary kidney transplant physician changes at an	
approved kidney transplant program.	

### 5A. Transplant Nephrology Fellowship Pathway

Physicians can meet the training requirements for a primary kidney transplant physician during a separate transplant nephrology fellowship if the following conditions are met:

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The physician completed at least 12 consecutive months of specialized training in transplantation under the direct supervision of a qualified kidney transplant physician and along with a kidney transplant surgeon at a kidney transplant program that performs 50 or more transplants each year. The training must have included at least 6 months of clinical inpatient transplant service. The remaining time must have consisted of transplant-related experience, such as experience in a tissue typing laboratory, on another solid organ transplant service, or conducting basic or clinical transplant research.

1. During the fellowship period, the physician was directly involved in the primary care of **30 or more** newly transplanted kidney recipients and continued the outpatient follow-up of these recipients for a minimum of 3 months from the time of transplant. If the physician's fellowship was longer than 12 months, the physician also must have been directly involved in the outpatient follow-up of at least 30 kidney recipients for an additional period of 3 consecutive months.

- During the fellowship period, the physician was directly involved in the evaluation of at least
   potential kidney recipients, including participation in selection committee meetings.
   This experience must be documented on the log provided.
- During the fellowship period the physician was directly involved in the evaluation of at least
   10 potential living kidney donors, including participation in selection committee meetings.
   This experience must be documented on the log provided.

4.	The physician has maintained a current working knowledge of kidney transplantation,
	defined as direct involvement in kidney transplant care in the last 2 years.
	Check all that apply
	$\Box$ The physician has experience with managing patients with end stage renal disease?
	$\square$ The physician has experience with the selection of appropriate recipients for
	transplantation.
	$\square$ The physician has experience with donor selection.
	$\square$ The physician has experience with histocompatibility and tissue typing.
	$\square$ The physician has experience with immediate postoperative patient care.
	$\square$ The physician has experience with the use of immunosuppressive therapy including side
	effects of the drugs and complications of immunosuppression.
	$\square$ The physician has experience with differential diagnosis of renal dysfunction in the
	allograft recipient.

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5. The physician has observed at least 3 kidney procurements, including at least 1 deceased donor and 1 living donor. The physician must have observed the evaluation, donation process, and management of these donors.

This experience must be documented on the log provided.

6. The physician has observed at least 3 kidney transplants. This experience must be documented on the log provided.

- 7. Provide the following letters with the application:
  - A letter from the director of the training program and the supervising qualified kidney transplant physician verifying that the physician has met the above requirements and is qualified to direct a kidney transplant program.
  - A letter of recommendation from the fellowship 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
    - 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 kidney transplantation.

The training requirements outlined above are in addition to other clinical requirements for general nephrology training.

#### 5B. **Clinical Experience Pathway**

A physician can meet the requirements for a primary kidney transplant physician through acquired clinical experience if the following conditions are met:

1. The physician has been directly involved in the primary care of **45 or more** newly transplanted kidney recipients and continued the outpatient follow-up of these recipients for transplant program.

a minimum of 3 months from the time of transplant. This patient care must have been provided over a 2 to 5-year period on an active kidney transplant service as the primary kidney transplant physician or under the direct supervision of a qualified transplant physician and in conjunction with a kidney transplant surgeon at a designated kidney

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This experience must be documented on the log provided.

2. The physician was directly involved in the evaluation of **at least 25** potential kidney recipients, including participation in selection committee meetings.

This experience must be documented on the log provided.

3. The physician was directly involved in the evaluation of **at least 10** potential living kidney donors, including participation in selection committee meetings.

This experience must be documented on the log provided.

The physician has maintained a current working knowledge of kidney transplantation,
defined as direct involvement in kidney transplant care in the last 2 years.
Check all that apply
$\ \square$ The physician has experience with managing patients with end stage renal disease.
$\square$ Does the physician have experience with the selection of appropriate recipients for
transplantation.
$\square$ The physician has experience with donor selection.
$\square$ The physician has experience with histocompatibility and tissue typing.
$\square$ The physician has experience with immediate postoperative patient care.
$\square$ The physician has experience with the use of immunosuppressive therapy including side
effects of the drugs and complications of immunosuppression.
$\square$ The physician has experience with differential diagnosis of renal dysfunction in the
allograft recipient.
$\ \square$ The physician has experience with histological interpretation of allograft biopsies.
$\ \square$ The physician has experience with interpretation of ancillary tests for renal dysfunction
$\square$ The physician has experience with long term outpatient care.
If a box is not checked, please provide an explanation:

5. The physician has observed **at least 3** kidney procurements, including at least 1 deceased donor and 1 living donor. The physician must have observed the evaluation, donation process, and management of these donors.

This experience must be documented on the log provided.

6. The physician has observed **at least 3** kidney transplants.

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

A letter from the qualified transplant physician or the kidney transplant surgeon who
has been directly involved with the proposed physician documenting the physician's
experience and competence.

- A letter of recommendation from the primary physician and transplant program director at the 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,
  - the individual's familiarity with and experience in adhering to OPTN obligations and compliance protocols, and

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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 kidney transplantation.

### 5C. Three-year Pediatric Nephrology Fellowship Pathway

A physician can meet the requirements for primary kidney transplant physician by completion of 3 years of pediatric nephrology fellowship training as required by the American Board of Pediatrics in a program accredited by the Residency Review Committee for Pediatrics (RRC-Ped) of the ACGME. The training must contain at least 6 months of clinical care for transplant patients, and the following conditions must be met:

1. During the 3-year training period the physician was directly involved in the primary care of 10 or more newly transplanted kidney recipients for at least 6 months from the time of transplant and followed 30 transplanted kidney recipients for at least 6 months, under the direct supervision of a qualified kidney transplant physician and in conjunction with a qualified kidney transplant surgeon. The pediatric nephrology program director may elect to have a portion of the transplant experience completed at another kidney transplant program in order to meet these requirements.

- 2. The experience caring for pediatric patients occurred with a qualified kidney transplant physician and surgeon at a kidney transplant program that performs an average of **at least 10** pediatric kidney transplants a year.
- During the fellowship period the physician was directly involved in the evaluation of at least
   potential kidney recipients, including participation in selection committee meetings.
   This experience must be documented on the log provided.

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

Check all that apply
$\square$ The physician has experience managing pediatric patients with end-stage renal
disease.
$\square$ The physician has experience with the selection of appropriate pediatric recipients for
transplantation.
$\square$ The physician has experience with donor selection.
$\ \square$ The physician has experience with histocompatibility and tissue typing.
$\square$ The physician has experience with immediate post-operative care including those
issues of management unique to the pediatric recipient.
$\ \square$ The physician has experience with fluid and electrolyte management.
$\square$ The physician has experience with the use of immunosuppressive therapy in the
pediatric recipient including side-effects of drugs and complications of
immunosuppression, the effects of transplantation and immunosuppressive agents on
growth and development.
$\square$ The physician has experience with differential diagnosis of renal dysfunction in the
allograft recipient.
$\square$ The physician has experience with the manifestation of rejection in the pediatric
patient.
$\ \square$ The physician has experience with histological interpretation of allograft biopsies?
$\ \square$ The physician has experience with interpretation of ancillary tests for renal
dysfunction.
$\square$ The physician has experience with long-term outpatient care of pediatric allograft
recipients including management of hypertension, nutritional support, and drug dosage,
including antibiotics, in the pediatric patient.
If a box is not checked, please provide an explanation:

5. The physician has observed **at least 3** kidney procurements, including at least 1 deceased donor and 1 living donor. The physician must have observed the evaluation, donation process and management of these donors.

- 6. The physician has observed **at least 3** kidney transplants involving a pediatric recipient. **This experience must be documented on the log provided.**
- 7. Provide the following letters with the application:

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- A letter from the director and the supervising qualified transplant physician and surgeon of the fellowship training program verifying that the physician has met the above requirements and is qualified to direct a kidney transplant program.
- A letter of recommendation from the fellowship 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,
  - 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 kidney transplantation.

### 5D. Twelve-month Pediatric Transplant Nephrology Fellowship Pathway

The requirements for the primary kidney transplant physician can be met during a separate pediatric transplant nephrology fellowship if the following conditions are met:

1. The physician is currently board certified in pediatric nephrology by the American Board of Pediatrics, the Royal College of Physicians and Surgeons of Canada, or is approved by the American Board of Pediatrics to take the certifying exam.

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

2. During the fellowship the physician was directly involved in the primary care of 10 or more newly transplanted kidney recipients for at least 6 months from the time of transplant and followed 30 transplanted kidney recipients for at least 6 months, under the direct supervision of a qualified kidney transplant physician and in conjunction with a qualified kidney transplant surgeon. The pediatric nephrology program director may elect to have a portion of the transplant experience completed at another kidney transplant program in order to meet these requirements.

This experience must be documented on the log provided.

3. During the four years that include the physician's three-year pediatric nephrology fellowship and twelve-month pediatric transplant nephrology fellowship, the physician was directly involved in the evaluation of **at least 25** potential kidney recipients, including participation in selection committee meetings.

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4.	The physician has maintained a current working knowledge of kidney transplantation,							
	defined as direct involvement in kidney transplant patient care <u>over the last 2 years</u> .							
	Check all that apply							
	$\ \square$ The physician has experience managing pediatric patients with end-stage renal disease.							
	$\Box$ The physician has experience with the selection of appropriate pediatric recipients for transplantation.							
	$\Box$ The physician has experience with donor selection.							
	$\Box$ The physician has experience with histocompatibility and tissue typing.							
	$\Box$ The physician has experience with immediate post-operative care including those							
	issues of management unique to the pediatric recipient.							
	$\ \square$ The physician has experience with fluid and electrolyte management.							
	$\ \square$ The physician has experience with the use of immunosuppressive therapy in the							
	pediatric recipient including side-effects of drugs and complications of							
	immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development.							
	$\Box$ The physician has experience with differential diagnosis of renal dysfunction in the allograft recipient.							
	$\Box$ The physician has experience with the manifestation of rejection in the pediatric patient.							
	$\Box$ The physician has experience with histological interpretation of allograft biopsies?							
	☐ The physician has experience with interpretation of ancillary tests for renal dysfunction.							
	☐ The physician has experience with long-term outpatient care of pediatric allograft							
	recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient.							
	If a box is not checked, please provide an explanation:							
	ij u box is not checkeu, pieuse provide un explanation.							
5.	The physician has observed <b>at least 3</b> kidney procurements, including at least 1 deceased donor and 1 living donor. The physician must have observed the evaluation, donation							
	process, and management of these donors.							
	This experience must be documented on the log provided.							
6.	The physician has observed <b>at least 3</b> kidney transplants involving a pediatric recipient. <b>This experience must be documented on the log provided.</b>							

- 7. Provide the following letters with the application:
  - A letter from the director and the supervising qualified transplant physician and surgeon of the fellowship training program verifying that the physician has met the above

requirements and is qualified to become the primary transplant physician of a designated kidney transplant program.

- A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining
  - the individual's overall qualifications to act as primary transplant physician,
  - o the individual's personal integrity and honesty,
  - the individual's familiarity with and experience in adhering to OPTN obligations and compliance protocols, and

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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 kidney transplantation.

### 5E. Combined Pediatric Nephrology Training and Experience Pathway

A physician can meet the requirements for primary kidney transplant physician if the following conditions are met:

- 1. The physician is currently board certified in pediatric nephrology by the American Board of Pediatrics, the Royal College of Physicians and Surgeons of Canada, or is approved by the American Board of Pediatrics to take the certifying exam.
  - Provide a copy of the physician's current board certification.
- 2. The physician gained a **minimum of 2 years of experience** during or after fellowship, or accumulated during both periods, at a kidney transplant program.
  - This experience must be documented on the log provided.
- 3. During the **2 or more years of accumulated experience**, the physician was directly involved in the primary care of **10 or more** newly transplanted kidney recipients for at least 6 months from the time of transplant and **followed 30** transplanted kidney recipients for at least 6 months, under the direct supervision of a qualified kidney transplant physician, along with a qualified kidney transplant surgeon.
  - This experience must be documented on the log provided.
- 4. The physician was directly involved in the evaluation of **at least 25** potential kidney recipients, including participation in selection committee meetings.
  - This experience must be documented on the log provided.
- 5. The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care <u>over the last 2 years</u>.

dysfunction.

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Ch	eck all that apply
	$\square$ The physician has experience managing pediatric patients with end-stage renal
	disease.
	$\ \square$ The physician has experience with the selection of appropriate pediatric recipients for
	transplantation.
	$\square$ The physician has experience with donor selection.
	$\ \square$ The physician has experience with histocompatibility and tissue typing.
	$\square$ The physician has experience with immediate post-operative care including those
	issues of management unique to the pediatric recipient.
	$\square$ The physician has experience with fluid and electrolyte management.
	$\square$ The physician has experience with the use of immunosuppressive therapy in the
	pediatric recipient including side-effects of drugs and complications of
	immunosuppression, the effects of transplantation and immunosuppressive agents on
	growth and development.
	$\square$ The physician has experience with differential diagnosis of renal dysfunction in the
	allograft recipient.
	$\square$ The physician has experience with the manifestation of rejection in the pediatric
	patient.
	$\square$ The physician has experience with histological interpretation of allograft biopsies?
	$\square$ The physician has experience with interpretation of ancillary tests for renal

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

including antibiotics, in the pediatric patient.

\_\_\_\_\_

☐ The physician has experience with long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage,

6. The physician has observed **at least 3** kidney procurements, including at least 1 deceased donor and 1 living donor. The physician must have observed the evaluation, donation process, and management of these donors.

- 7. The physician has observed **at least 3** kidney transplants involving a pediatric recipient. **This experience must be documented on the log provided.**
- 8. Provide the following letters with the application:
  - A letter from the supervising qualified transplant physician and surgeon who were directly involved with the physician documenting the physician's experience and competence.

• A letter of recommendation from the fellowship 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,
- the individual's familiarity with and experience in adhering to OPTN obligations and compliance protocols, and

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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 kidney transplantation.

### 5F. Conditional Approval for Primary Transplant Physician

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

1. The physician has been involved in the primary care of **23 or more** newly transplanted kidney recipients, and has continued the outpatient follow-up of these patients for at least 3 months from the time of their transplant.

This experience must be documented on the log provided.

 The physician was directly involved in the evaluation of at least 25 potential kidney recipients, including participation in selection committee meetings.

This experience must be documented on the log provided.

 The physician was directly involved in the evaluation of at least 10 potential living kidney donors, including participation in selection committee meetings.

4.	The physician has maintained a current working knowledge of kidney transplantation,
	defined as direct involvement in kidney transplant care in the last 2 years.
	Check all that apply
	$\ \square$ The physician has experience with managing patients with end stage renal disease.
	$\square$ The physician has experience with the selection of appropriate recipients for
	transplantation.
	$\square$ The physician has experience with donor selection.
	$\square$ The physician has experience with histocompatibility and tissue typing.
	$\Box$ The physician has experience with immediate postoperative patient care.

6. The physician has observed **at least 3** kidney procurements, including at least 1 deceased donor and 1 living donor. The physician must have observed the evaluation, donation process, and management of these donors.

- The physician has observed at least 3 kidney transplants.
   This experience must be documented on the log provided.
- 8. **Provide documentation** that the program has established and documented a **consulting relationship** with counterparts at another kidney transplant program.
- 9. Provide documentation that the transplant program will submit activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress to meet the required involvement in the primary care of 45 or more kidney transplant recipients, or that the program is making sufficient progress in recruiting a physician who meets all requirements for primary kidney transplant physician and 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.
- 10. Provide the following letters with the application:

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- A letter from the supervising qualified transplant physician and surgeon who were directly involved with the physician documenting the physician's experience and competence.
- A letter of recommendation from the primary physician and director at the 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,
  - 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 kidney transplantation.

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## **Part 7: Pediatric Transplant Component**

### Kidney Transplant Programs that Register Candidates Less than 18 Years Old

A designated kidney 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 kidney transplant program must identify a qualified primary pediatric kidney transplant surgeon and a qualified primary pediatric kidney transplant physician.

# Part 7A: Primary Pediatric Kidney Transplant Surgeon Requirements

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	1.	<ol> <li>Name of Proposed Primary Pediatric Kidney Transplant Surgeon (as indicate Assessment):</li> </ol>	d in Certificate of
		Name NPI #	·
	2.	2. Check yes or no for each of the following. Provide documentation where app	olicable:
Ye	s No	s No	
		☐ 2a. Does the surgeon have an M.D., D.O., or equivalent degree from another coulicense to practice medicine in the hospital's state or jurisdiction?  Provide a copy of the surgeon's resume/CV.	ntry, with a curren
		☐ 2b. Has the surgeon been accepted onto the hospital's medical staff, and is practional hospital?	ticing on site at this
		Provide documentation from the hospital credentialing committee that is surgeon's state license, board certification, training, and transplant content education, and that the surgeon is currently a member in good standing of the staff.	ontinuing medica
	3.	3. Certification. Check one and provide corresponding documentation:	
		3a. The surgeon is currently certified by the American Board of Surgery, the An Urology, the American Board of Osteopathic Surgery, or the Royal College of P Surgeons of Canada.	-
		Provide a copy of the surgeon's current board certification.  3b. The surgeon has just completed training and is pending certification by the of Urology. Therefore, the program is requesting conditional approval for 16 n surgeon time to complete board certification, with the possibility of renewal for 16-month period.	nonths to allow the
		Provide documentation supporting that training has been completed and cerpending, which must include the anticipated date of board certification and is in the process to be certified.	-
		3c. The surgeon is without certification by the American Board of Surgery, the Urology, the American Board of Osteopathic Surgery, or the Royal College of P Surgeons of Canada.  If this option is selected:	-
		<ul> <li>The surgeon must be ineligible for American board certification. Provide a the individual is ineligible:</li> </ul>	ın explanation why

5.

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

- Provide at least 2 two letters of recommendation from directors of designated transplant programs not employed by the applying hospital that address
  - o why an exception is reasonable,
  - o the individual's overall qualifications to act as a primary kidney transplant surgeon,

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- o the individual's personal integrity and honesty,
- the individual's familiarity with and experience in adhering to OPTN obligations and compliance protocols, and
- o any other matters judged appropriate.
- 4. Summarize the surgeon's training and experience in transplant:

Training and	Approved Fellowship Program?	Date (MM/DD/YY)		Transplant	Program	# Kidney Transplants	# Kidney Transplants as 1st	# of Kidney Procurements as Primary or	
Experience	Y/N	Start	End	Hospital	Director	as Primary	Assistant	1 <sup>st</sup> Assistant	
Fellowship Training									
Experience Post Fellowship									

Which of the following pathways is the proposed primary surgeon applying (check one, and complete the corresponding pathway section below):
<ul> <li>☐ The <b>fellowship pathway</b>, as described in <i>Section 5A: Formal 2-year Transplant Fellowship Pathway</i> below.</li> <li>☐ The <b>clinical experience pathway</b>, as described in <i>Section 5B: Clinical Experience Pathway</i> below.</li> </ul>
5A. Formal 2-year Transplant Fellowship Pathway
Surgeons can meet the training requirements for primary kidney transplant surgeon by completing a formal 2-year surgical transplant fellowship if the following conditions are met:

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1. The surgeon performed **at least 30** kidney transplants as the primary surgeon or first assistant during the 2-year fellowship period.

This experience must be documented on the log provided.

2. The surgeon performed **at least 15** kidney procurements as primary surgeon or first assistant. At least 10 of these procurements must be from deceased donors. These procurements must have been performed anytime during the surgeon's fellowship and the two years immediately following fellowship completion.

This experience must be documented on the log provided.

3.	The surgeon has maintained a current working knowledge of kidney transplantation, defined
	as direct involvement in kidney transplant patient care in the last 2 years.
	Check all that apply
	$\ \square$ The surgeon has experience with managing patients with end stage renal disease.
	$\square$ The surgeon has experience with the selection of appropriate recipients for
	transplantation.
	$\square$ The surgeon has experience with donor selection.
	$\ \square$ The surgeon has experience with histocompatibility and tissue typing.
	$\square$ The surgeon has experience with performing the transplant operation.
	$\ \square$ The surgeon has experience with immediate postoperative and continuing inpatient care
	$\square$ The surgeon has experience with the use of immunosuppressive therapy including side
	effects of the drugs and complications of immunosuppression.
	$\square$ The surgeon has experience with differential diagnosis of renal dysfunction in the
	allograft recipient.
	$\ \square$ The surgeon has experience with histological interpretation of allograft biopsies.
	$\ \square$ The surgeon has experience with interpretation of ancillary tests for renal dysfunction.
	$\square$ The surgeon has experience with long term outpatient care.
	If a box is not checked, please provide an explanation:

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

- A letter from the director of the training program and chair of the department or hospital credentialing committee verifying that the surgeon has met the above requirements and is qualified to direct a kidney transplant program.
- A letter of recommendation from the fellowship training program's primary surgeon and transplant program director outlining
  - o the individual's overall qualifications to act as primary transplant surgeon,
  - o the individual's personal integrity and honesty,
  - 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.

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• A letter from the surgeon that details the training and experience the surgeon has gained in kidney transplantation.

### 5B. Clinical Experience Pathway

allograft recipient?

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

The surgeon has performed 45 or more kidney transplants over a 2 to 5-year period as primary surgeon, co-surgeon, or first assistant at a designated kidney transplant program.
 Of these 45 kidney transplants, 23 or more must have been performed as primary surgeon or co-surgeon. Each year of the surgeon's experience must be substantive and relevant and include pre-operative assessment of kidney transplant candidates, performance of transplants as primary surgeon or first assistant, and post-operative care of kidney recipients.

This experience must be documented on the log provided.

2. The surgeon has performed at least 15 kidney procurements as primary surgeon, co-surgeon, or first assistant. Of these 15 kidney procurements, at least 8 must have been performed as primary surgeon or co-surgeon. At least 10 of these procurements must be from deceased donors.

3. The surgeon has maintained a current working knowledge of kidney transplantation, defined

as direct involvement in kidney transplant patient care in the last 2 years.
Check all that apply
$\Box$ Does the surgeon have experience with managing patients with end stage renal disease?
$\square$ Does the surgeon have experience with the selection of appropriate recipients for
transplantation?
$\square$ Does the surgeon have experience with donor selection?
$\square$ Does the surgeon have experience with histocompatibility and tissue typing?
$\square$ Does the surgeon have experience with performing the transplant operation?
$\square$ Does the surgeon have experience with immediate postoperative and continuing
inpatient care?
$\ \square$ Does the surgeon have experience with the use of immunosuppressive therapy including
side effects of the drugs and complications of immunosuppression?
$\square$ Does the surgeon have experience with differential diagnosis of renal dysfunction in the

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	<ul> <li>□ Does the surgeon have experience with his dysfunction?</li> <li>□ Does the surgeon have experience with in dysfunction?</li> <li>□ Does the surgeon have experience with low of the surgeon have experience with his dysfunction?</li> </ul>	long term outpatient care?		
4.	Provide the following letters along with the	application:		
	hospital credentialing committee verifying qualifications and is qualified to direct a life of recommendation from the fell transplant program director outlining  o the individual's overall qualification the individual's personal integrity the individual's familiarity with a life and compliance protocols, and life on any other matters judged appropriate MPSC may request additional resphysician, primary surgeon, director, program previously served by the sur	kidney transplant program lowship training program's primary surgeon and ions to act as primary transplant surgeon, y and honesty, nd experience in adhering to OPTN obligations oriate. commendation letters from the primary or others affiliated with any transplant		
6. <b>Pe</b>	diatric-Specific Requirements			
	first assistant, in recipients less than of these kidney transplants must hav	· · · · · · · · · · · · · · · · · · ·		
	transplantation, defined as direct inv care within the last 2 years.  Check all that apply  The surgeon has experience with renal disease.	nt working knowledge of pediatric kidney olvement in pediatric kidney transplant patient managing pediatric patients with end stage the selection of appropriate pediatric recipients		

 $\square$  The surgeon has experience with donor selection.

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| The surgeon has experience with HLA typing.
| The surgeon has experience with performing the transplant operation.
| The surgeon has experience with immediate postoperative and continuing inpatient care.
| The surgeon has experience with the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression.
| The surgeon has experience with differential diagnosis of renal dysfunction in the allograft recipient.
| The surgeon has experience with histological interpretation of allograft biopsies.
| The surgeon has experience with interpretation of ancillary tests for renal dysfunction.
| The surgeon has experience with long term outpatient care.
| If a box is not checked, please provide an explanation:

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# Part 7B: Primary Pediatric Kidney Transplant Physician Requirements

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1	l.	Name of Proposed Primary Pediatric Kidney Transplant Physician (as indicated in Certificate of Assessment):				
		Name NPI #				
2	2.	Check yes or no for each of the following. Provide documentation where applicable:				
⁄es I	No					
		2a. Does the physician have an M.D., D.O., or equivalent degree from another country, with courrent license to practice medicine in the hospital's state or jurisdiction?  Provide a copy of the physician's resume/CV.				
		2b. Has the physician been accepted onto the hospital's medical staff, and is practicing on site at this hospital?				
		Provide documentation from the hospital credentialing committee that it has verified the ohysician's state license, board certification, training, and transplant continuing medical education, and that the physician is currently a member in good standing of the hospital's medical staff.				
\$	3.	Certification. Check one and provide corresponding documentation:				
		3a. The physician is currently certified in nephrology by the American Board of Internal Medicine the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada.  Provide a copy of the physician's current board certification.				
		3b. The physician is without certification in nephrology by the American Board of Interna Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada.				
		<ul> <li>The physician must be ineligible for American board certification. Provide an explanation why the individual is ineligible:</li> </ul>				
		Provide a plan for continuing education that is comparable to American board     maintenance of contification				
		<ul> <li>maintenance of certification</li> <li>Provide at least 2 two letters of recommendation from directors of designated transplant programs not employed by the applying hospital that address</li> </ul>				
		<ul> <li>why an exception is reasonable,</li> <li>the individual's overall qualifications to act as a primary kidney transplant physician,</li> <li>the individual's personal integrity and honesty,</li> <li>the individual's familiarity with and experience in adhering to OPTN obligations and</li> </ul>				
		compliance protocols, and  o any other matters judged appropriate.				

5.

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

	Approved	Date (MM/DD/YY)				#Kidney Patients Followed		
Training and Experience	Fellowship Program? Y/N	Start	End	Transplant Hospital	Program Director	Pre	Peri	Post
Fellowship Training								
Experience Post Fellowship								

Which of the following pathways is the proposed primary pediatric physician applying (check one, and complete the corresponding pathway section below):
☐ The <b>3-year pediatric nephrology fellowship pathway</b> , as described in <i>Section 5A: Three-year Pediatric Nephrology Fellowship Pathway</i> below.
☐ The <b>12-month pediatric transplant nephrology fellowship pathway</b> , as described in <i>Section</i>
5B: Twelve-month Pediatric Transplant Nephrology Fellowship Pathway below.  ☐ The combined pediatric nephrology training and experience pathway, as described in Section 5C: Combined Pediatric Nephrology Training and Experience Pathway below.

### 5A. Three-year Pediatric Nephrology Fellowship Pathway

A physician can meet the requirements for primary kidney transplant physician by completion of 3 years of pediatric nephrology fellowship training as required by the American Board of Pediatrics in a program accredited by the Residency Review Committee for Pediatrics (RRC-Ped) of the ACGME. The training must contain at least 6 months of clinical care for transplant patients, and the following conditions must be met:

1. During the 3-year training period the physician was directly involved in the primary care of **10 or more** newly transplanted kidney recipients for at least 6 months from the time of transplant and followed 30 transplanted kidney recipients for at least 6 months, under the direct supervision of a qualified kidney transplant physician and in conjunction with a qualified kidney transplant surgeon. The pediatric nephrology program director may elect to

have a portion of the transplant experience completed at another kidney transplant program in order to meet these requirements.

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- 2. The experience caring for pediatric patients occurred with a qualified kidney transplant physician and surgeon at a kidney transplant program that performs an average of **at least 10** pediatric kidney transplants a year.
- During the fellowship period the physician was directly involved in the evaluation of at least
   potential kidney recipients, including participation in selection committee meetings.
   This experience must be documented on the log provided.

4.	The physician has maintained a current working knowledge of kidney transplantation,
	defined as direct involvement in kidney transplant patient care <u>over the last 2 years</u> .
	Check all that apply
	$\square$ The physician has experience managing pediatric patients with end-stage renal
	disease.
	$\ \square$ The physician has experience with the selection of appropriate pediatric recipients fo transplantation.
	$\square$ The physician has experience with donor selection.
	$\square$ The physician has experience with histocompatibility and tissue typing.
	$\square$ The physician has experience with immediate post-operative care including those
	issues of management unique to the pediatric recipient.
	$\square$ The physician has experience with fluid and electrolyte management.
	$\square$ The physician has experience with the use of immunosuppressive therapy in the
	pediatric recipient including side-effects of drugs and complications of
	immunosuppression, the effects of transplantation and immunosuppressive agents on
	growth and development.
	$\ \square$ The physician has experience with differential diagnosis of renal dysfunction in the allograft recipient.
	$\Box$ The physician has experience with the manifestation of rejection in the pediatric
	patient.
	☐ The physician has experience with histological interpretation of allograft biopsies?
	☐ The physician has experience with interpretation of ancillary tests for renal
	dysfunction.
	$\square$ The physician has experience with long-term outpatient care of pediatric allograft
	recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient.
	If a box is not checked, please provide an explanation:

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5. The physician has observed **at least 3** kidney procurements, including at least 1 deceased donor and 1 living donor. The physician must have observed the evaluation, donation process and management of these donors.

This experience must be documented on the log provided.

6. The physician has observed **at least 3** kidney transplants involving a pediatric recipient. **This experience must be documented on the log provided.** 

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

- A letter from the director and the supervising qualified transplant physician and surgeon of the fellowship training program verifying that the physician has met the above requirements and is qualified to direct a kidney transplant program.
- A letter of recommendation from the fellowship 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,
  - 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 kidney transplantation.

### 5B. Twelve-month Pediatric Transplant Nephrology Fellowship Pathway

The requirements for the primary kidney transplant physician can be met during a separate pediatric transplant nephrology fellowship if the following conditions are met:

- 1. The physician is currently board certified in pediatric nephrology by the American Board of Pediatrics, the Royal College of Physicians and Surgeons of Canada, or is approved by the American Board of Pediatrics to take the certifying exam.
  - Provide a copy of the physician's current board certification.
- 2. During the fellowship the physician was directly involved in the primary care of **10** or more newly transplanted kidney recipients for at least 6 months from the time of transplant and followed 30 transplanted kidney recipients for at least 6 months, under the direct supervision of a qualified kidney transplant physician and in conjunction with a qualified kidney transplant surgeon. The pediatric nephrology program director may elect to have a portion

of the transplant experience completed at another kidney transplant program in order to meet these requirements.

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This experience must be documented on the log provided.

3. During the four years that include the physician's three-year pediatric nephrology fellowship and twelve-month pediatric transplant nephrology fellowship, the physician was directly involved in the evaluation of **at least 25** potential kidney recipients, including participation in selection committee meetings.

4.	The physician has maintained a current working knowledge of kidney transplantation,
	defined as direct involvement in kidney transplant patient care over the last 2 years.
	Check all that apply
	$\ \square$ The physician has experience managing pediatric patients with end-stage renal
	disease.
	$\ \square$ The physician has experience with the selection of appropriate pediatric recipients for
	transplantation.
	$\square$ The physician has experience with donor selection.
	$\ \square$ The physician has experience with histocompatibility and tissue typing.
	$\square$ The physician has experience with immediate post-operative care including those
	issues of management unique to the pediatric recipient.
	$\ \square$ The physician has experience with fluid and electrolyte management.
	$\ \square$ The physician has experience with the use of immunosuppressive therapy in the
	pediatric recipient including side-effects of drugs and complications of
	immunosuppression, the effects of transplantation and immunosuppressive agents on
	growth and development.
	$\ \square$ The physician has experience with differential diagnosis of renal dysfunction in the allograft recipient.
	$\Box$ The physician has experience with the manifestation of rejection in the pediatric patient.
	$\square$ The physician has experience with histological interpretation of allograft biopsies?
	$\ \square$ The physician has experience with interpretation of ancillary tests for renal
	dysfunction.
	$\square$ The physician has experience with long-term outpatient care of pediatric allograft
	recipients including management of hypertension, nutritional support, and drug dosage,
	including antibiotics, in the pediatric patient.
	If a box is not checked, please provide an explanation:

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5. The physician has observed **at least 3** kidney procurements, including at least 1 deceased donor and 1 living donor. The physician must have observed the evaluation, donation process, and management of these donors.

This experience must be documented on the log provided.

6. The physician has observed **at least 3** kidney transplants involving a pediatric recipient. **This experience must be documented on the log provided.** 

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

- A letter from the director and the supervising qualified transplant physician and surgeon
  of the fellowship training program verifying that the physician has met the above
  requirements and is qualified to become the primary transplant physician of a
  designated kidney transplant program.
- A letter of recommendation from the fellowship 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,
  - 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 kidney transplantation.

### 5C. Combined Pediatric Nephrology Training and Experience Pathway

A physician can meet the requirements for primary kidney transplant physician if the following conditions are met:

- The physician is currently board certified in pediatric nephrology by the American Board of Pediatrics, the Royal College of Physicians and Surgeons of Canada, or is approved by the American Board of Pediatrics to take the certifying exam.
  - Provide a copy of the physician's current board certification.
- 2. The physician gained a **minimum of 2 years of experience** during or after fellowship, or accumulated during both periods, at a kidney transplant program.
  - This experience must be documented on the log provided.

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qualified kidney transplant surgeon.

3. During the **2 or more years of accumulated experience**, the physician was directly involved in the primary care of **10 or more** newly transplanted kidney recipients for at least 6 months from the time of transplant and **followed 30** transplanted kidney recipients for at least 6 months, under the direct supervision of a qualified kidney transplant physician, along with a

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This experience must be documented on the log provided.

4. The physician was directly involved in the evaluation of **at least 25** potential kidney recipients, including participation in selection committee meetings.

5.	The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care over the last 2 years.
	Check all that apply
	$\Box$ The physician has experience managing pediatric patients with end-stage renal
	disease.
	$\square$ The physician has experience with the selection of appropriate pediatric recipients for transplantation.
	$\square$ The physician has experience with donor selection.
	$\ \square$ The physician has experience with histocompatibility and tissue typing.
	$\Box$ The physician has experience with immediate post-operative care including those issues of management unique to the pediatric recipient.
	☐ The physician has experience with fluid and electrolyte management.
	☐ The physician has experience with the use of immunosuppressive therapy in the
	pediatric recipient including side-effects of drugs and complications of
	immunosuppression, the effects of transplantation and immunosuppressive agents on
	growth and development.
	$\Box$ The physician has experience with differential diagnosis of renal dysfunction in the allograft recipient.
	$\Box$ The physician has experience with the manifestation of rejection in the pediatric
	patient.
	☐ The physician has experience with histological interpretation of allograft biopsies?
	☐ The physician has experience with interpretation of ancillary tests for renal
	dysfunction.
	$\square$ The physician has experience with long-term outpatient care of pediatric allograft
	recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient.
	If a box is not checked, please provide an explanation:

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6. The physician has observed **at least 3** kidney procurements, including at least 1 deceased donor and 1 living donor. The physician must have observed the evaluation, donation

process, and management of these donors.

This experience must be documented on the log provided.

7. The physician has observed **at least 3** kidney transplants involving a pediatric recipient. **This experience must be documented on the log provided.** 

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

- A letter from the supervising qualified transplant physician and surgeon who were directly involved with the physician documenting the physician's experience and competence.
- A letter of recommendation from the fellowship 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,
  - 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 kidney transplantation.

### Part 7C: Conditional Approval for a Pediatric Component

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

Check one, and complete the corresponding portions of the application. Provide supporting documentation where applicable:

- Option A. The program has a qualified primary pediatric kidney **physician** who meets *all* of the requirements described in application *Part 5C: Primary Pediatric Kidney Transplant Physician Requirements* and a **surgeon** who meets *all* of the following requirements:
  - The surgeon meets all of the requirements described in Part 3: Primary Kidney Transplant Surgeon Requirements, including completion of at least one of the following training or experience pathways:
    - O The **formal 2-year transplant fellowship pathway** as described in application *Part 3*, *Section 5A: Formal 2-year Transplant Fellowship Pathway*

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- O The **kidney transplant program clinical experience pathway**, as described in application *Part 3, Section 5B: Clinical Experience Pathway*
- Provide documentation that the surgeon has performed at least 5 kidney transplants, as the primary surgeon or first assistant, in recipients less than 18 years old at the time of transplant. At least 1 of these kidney transplants must have been in recipients less than 6 years old or weighing less than 25 kilograms at the time of transplant. These transplants must have been performed during or after fellowship, or across both periods.

The surgeon maintained a current working knowledge of pediatric kidney transplantation, defined as direct involvement in pediatric kidney transplant patient care.
in the last 2 years. This includes <b>(check all that apply)</b>
☐ the management of pediatric patients with end stage renal disease
$\Box$ the selection of appropriate pediatric recipients for transplantation
☐ donor selection
$\square$ histocompatibility and HLA typing
$\square$ performing the pediatric transplant operation
$\ \square$ immediate postoperative and continuing inpatient care
$\square$ the use of immunosuppressive therapy including side effects of the drugs and
complications of immunosuppression
$\ \square$ differential diagnosis of renal dysfunction in the allograft recipient
$\square$ histological interpretation of allograft biopsies
$\ \square$ interpretation of ancillary tests for renal dysfunction
$\square$ long term outpatient care
<b>Option B.</b> The program has a qualified primary pediatric kidney <b>surgeon</b> who meets <i>all</i> of the

requirements described in application *Part 5B: Primary Pediatric Kidney Transplant Surgeon Requirements* and a **physician** who meets *all* of the following requirements:

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 The physician is currently board certified in pediatric nephrology by the American Board of Pediatrics or the foreign equivalent, or is approved by the American Board of Pediatrics to take the certifying exam.

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

- The physician gained a **minimum of 2 years of experience** during or after fellowship, or accumulated during both periods, at a kidney transplant program.
- During the 2 or more years of accumulated experience, the physician was directly involved in the
  primary care of 5 or more newly transplanted kidney recipients and followed 15 newly
  transplanted kidney recipients for at least 6 months from the time of transplant, under the direct
  supervision of a qualified kidney transplant physician, along with a qualified kidney transplant
  surgeon.

•	The physician has maintained a current working knowledge of pediatric kidney transplantation,
	defined as direct involvement in kidney transplant patient care <u>during the past 2 years</u> .
	This includes (check all that apply)
	$\square$ the management of pediatric patients with end-stage renal disease
	$\square$ the selection of appropriate pediatric recipients for transplantation
	☐ donor selection
	$\square$ histocompatibility and HLA typing
	$\square$ immediate post-operative care including those issues of management unique to the
	pediatric recipient
	$\square$ fluid and electrolyte management
	$\square$ the use of immunosuppressive therapy in the pediatric recipients including side-
	effects of drugs and complications of immunosuppression
	$\square$ the effects of transplantation and immunosuppressive agents on growth and
	development
	$\square$ differential diagnosis of renal dysfunction in the allograft recipient
	$\square$ manifestation of rejection in the pediatric patient
	$\square$ histological interpretation of allograft biopsies
	$\square$ interpretation of ancillary tests for renal dysfunction
	$\ \square$ long-term outpatient care of pediatric allograft recipients including management of
	hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric
	patient

- The physician has observed at least 3 organ procurements and at least 3 pediatric kidney transplants. The physician should also have observed the evaluation, the donation process, and management of at least 3 multiple organ donors who donated a kidney.
  - This experience must be documented on the log provided.
- Provide the following letters with the application:

A letter from the supervising qualified transplant physician and surgeon who were

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- directly involved with the physician documenting the physician's experience and competence.
- A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining
  - the individual's overall qualifications to act as a primary transplant physician,
  - the individual's personal integrity and honesty,
  - the individual's familiarity with and experience in adhering to OPTN obligations,
  - and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary pediatric 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 kidney transplantation.

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

# Part 8: Kidney Transplant Programs that Perform Living Donor Recovery

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

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•	recovery hospitals must meet all the requirements of a designated kidney transplant program st also have the following:
-	stions 1 through 4, check to attest that the program has adequate resources in place for living idney recovery:
1. Pro	tocols and Resources for Evaluations
	The kidney recovery hospital has protocols and resources in place for performing living donor evaluations.
2. Sur	gical Resources
	The kidney recovery hospital has surgical resources on site for open or laparoscopic living donor kidney recoveries.
3. Livii	ng Donor Medical Evaluation
	The kidney recovery hospital has the clinical resources available to assess the medical condition of and specific risks to the living donor.
4. Livii	ng Donor Psychological Evaluation
	The kidney recovery hospital has the clinical resources to perform a psychosocial evaluation of the living donor.
5. <b>Ind</b>	ependent Living Donor Advocate (ILDA)
	The kidney recovery hospital must have an independent living donor advocate (ILDA) who is not involved with the evaluation or treatment decisions of the potential recipient, and is a knowledgeable advocate for the living donor. The ILDA must be independent of the decision to transplant the potential recipient and follow the protocols that outline the duties and responsibilities of the ILDA according to OPTN <i>Policy 14.2: Independent Living Donor Advocate (ILDA) Requirements</i> .  Name of Independent Living Donor Advocate (ILDA):

Department of Health and Human Services OMB No. 0915-0184 Health Resources and Services Administration Expiration Date: 08/31/2023 6. Primary Open Living Donor Kidney Surgeon A kidney donor surgeon who performs open living donor nephrectomies must be on site. Name of Proposed Open Living Donor Nephrectomies Surgeon: NPI# Name An open living donor nephrectomies must meet *one* of the following criteria. Check one and provide corresponding documentation ☐ Completion of a **formal 2-year surgical transplant fellowship in kidney** at a fellowship program approved by the American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or other recognized fellowship training program accepted by the OPTN Contractor as described in Bylaw Section E.4.A: Transplant Surgeon Fellowship Training Programs. Provide this surgeon's resume/CV with the application. ☐ Completion of **at least 10** open nephrectomies, including deceased donor nephrectomies or the removal of diseased kidneys, as primary surgeon, co-surgeon, or first assistant. At least 5 of these open nephrectomies must have been performed as the primary surgeon or co-surgeon. This experience must be documented on the log provided.

### 7. Primary Laparoscopic Living Donor Kidney Surgeon

A surgeon who performs laparoscopic living donor kidney recoveries must be on site and must meet the following criteria:

Name of Proposed Primary Laparoscopic Living Donor Kidney Surgeon:				
Name	NPI #			
$\Box$ The surgeon must have completed <b>at least 15</b> ld	aparoscopic nephrectomies in the last 5 years			
as primary surgeon, co-surgeon, or first assistant.				
This experience must be documented on the log pr	rovided.			
$\square$ <b>Seven</b> of these nephrectomies must have been p	performed as primary surgeon or co-surgeon,			
and this role should be documented by a letter from	n the fellowship program director, program			
director, division chief, or department chair from the program where the surgeon gained this				
experience.				

Provide the letter with the application.

### **PUBLIC BURDEN STATEMENT**

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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 paperwork@hrsa.gov.