OPTN Membership Application for Kidney Transplant Programs

CERTIFICATION

The undersigned, a duly authorized representative of the applicant, does hereby certify that the answers and attachments to this application are true, correct and complete, to the best of his or her knowledge after investigation. I understand that the intentional submission of false data to the OPTN may result in action by the Secretary of the Department of Health and Human Services, and/or civil or criminal penalties. By submitting this application to the OPTN, the applicant agrees: (i) to be bound by OPTN Obligations, including amendments thereto, if the applicant is granted membership and (ii) to be bound by the terms, thereof, including amendments thereto, in all matters relating to consideration of the application without regard to whether or not the applicant is granted membership.

OPTN Representative

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

Email Address Printed Name Signature Position ___ **Printed Name** Signature **Email Address** Position _____ **Printed Name Email Address** Signature Position _____ **Email Address Printed Name** Signature Position **Printed Name** Signature **Email Address**

Department of Health and Human Services Health Resources and Services Administration

Printed Name

Position

Signature

OMB No. 0915-0184

Expiration Date: 08/31/2023

Email Address

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

Expiration Date: 08/31/2023

Part 1: General Information

lame of Transplant Hospital:					
OPTN Member Code (4 Let	ters):				
Transplant Hospital Addres	ss (where transpla	ants occur)			
Street:		Ste:	Phone #:		
City:	ST:	Zip:	Fax #:		
Name of Person Completin	g Form:		Title:		
Email Address of Person Co	ompleting Form: _				
Date Form is submitted to	OPTN Contractor:	·			

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 new individual listed.

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:
Fmail·

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 Kidney Transplant Surgeon Requirements

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Name of Proposed Primary Kidney Transplant Surgeon (as indicated in Certificate of Assessment):						
	NPI #					
Check yes or no for each of the following. Provide docu	mentation where applicable:					
)						
current license to practice medicine in the hospital's state	•					
	Name NPI # Pach of the following. Provide documentation where applicable: have an M.D., D.O., or equivalent degree from another country, with a tice medicine in the hospital's state or jurisdiction? surgeon's resume/CV. en accepted onto the hospital's medical staff, and is practicing on site at this on from the hospital credentialing committee that it has verified the use, board certification, training, and transplant continuing medical the surgeon is currently a member in good standing of the hospital's one and provide corresponding documentation: Trently certified by the American Board of Surgery, the American Board of an Board of Osteopathic Surgery, or the Royal College of Physicians and the program is requesting conditional approval for 16 months to allow the object board certification, with the possibility of renewal for one additional ion supporting that training has been completed and certification is include the anticipated date of board certification and where the surgeon exertified. Schout certification by the American Board of Surgery, the American Board of an Board of Osteopathic Surgery, or the Royal College of Physicians and or pending certification by the American Board of Urology. The pending certification by the American Board of Urology. The pending certification by the American Board of Urology. The pending certification by the American Board of Urology.					
surgeon's state license, board certification, training	, and transplant continuing medical					
Certification. Check one and provide corresponding doc	cumentation:					
- · · · · · · · · · · · · · · · · · · ·						
Provide a copy of the surgeon's current board certificat	ion.					
of Urology. Therefore, the program is requesting condition surgeon time to complete board certification, with the po	onal approval for 16 months to allow the					
-	en completed and certification is					
is in the process to be certified.						
Urology, the American Board of Osteopathic Surgery, or	the Royal College of Physicians and					
 The surgeon must be ineligible for American boar why the individual is ineligible: 	rd certification. Provide an explanation					
2	Name Check yes or no for each of the following. Provide documentation surgeon is currently certification. Check one and provide corresponding documentation. Check one and provide corresponding and is pending. Provide a copy of the surgeon is currently a member of Urology, The refore, the program is requesting and is pending. Provide documentation from the hospital credentialises and the surgeon is currently a member of Urology. Therefore, the program is requesting conditions are surgeon time to complete board certification, with the pending, which must include the anticipated date of bois in the process to be certified. 3c. The surgeon is without certification by the American Book of Osteopathic Surgery, or Surgeons of Canada. Provide documentation supporting that training has be pending, which must include the anticipated date of bois in the process to be certified. 3c. The surgeon is without certification by the American Urology, the American Board of Osteopathic Surgery, or Surgeons of Canada or pending certification by the American Urology, the American Board of Osteopathic Surgery, or Surgeons of Canada or pending certification by the American Urology, the American Board of Osteopathic Surgery, or Surgeons of Canada or pending certification by the American If this option is selected:					

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

Training and Experienc e Fellowshi p Training	Approve d Fellowsh ip Program ? Y/N	(M	ete M/ 'YY) End	Transplan t Hospital	Program Director	# Kidney Transplan ts as Primary	# Kidney Transplan ts as 1st Assistant	# of Kidney Procureme nts as Primary or 1 st Assistant
Experienc e Post Fellowshi p								

5.	Which of the following pathways is the proposed primary surgeon applying (check one, and complete the corresponding pathway section below):
	☐ The fellowship pathway , as described in <i>Section 55A</i> . Formal 2-year Transplant Fellowship Pathway below.
	☐ The clinical experience pathway , as described in <i>Section 55B. Clinical Experience Pathway</i>
	below.

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 a log that includes the date of transplant, role of the surgeon, medical record number or other unique identifier, and the fellowship director's signature.
- 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 a log that includes the date of procurement and Donor ID.

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.
\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.
\Box 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,
 - 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.

• 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:

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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 a log that includes the date of transplant, the role of the surgeon, and medical record number or other unique identifier.

2. The surgeon has performed **at least 15** kidney procurements as primary surgeon, cosurgeon, 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.

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

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 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.
	\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 along with the application:

- 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,
 - 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.

• 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.	Name of Proposed Primary Kidney Transplant Physician (as indicated in Certificate of Assessment):
	Name NPI #
2.	Check yes or no for each of the following. Provide documentation where applicable:
es No	o
	2a. Does the physician have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction? Provide a copy of the physician's resume/CV.
	2b. Has the physician been accepted onto the hospital's medical staff, and is practicing on site at this hospital?
	Provide documentation from the hospital credentialing committee that it has verified the physician's state license, board certification, training, and transplant continuing medical education, and that the physician is currently a member in good standing of the hospital's medical staff.
3.	Certification. Check one and provide corresponding documentation:
	3a. The physician is currently certified in 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.
	 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, the individual's overall qualifications to act as a primary kidney transplant physician, the individual's personal integrity and honesty,

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

Training and Experienc e	Approved Fellowshi p	Fellowshi (MM/DD/				#Kidney Patients Followed		
	Program? Y/N	Start	End	Transplant Hospital	Program Director	Pre	Peri	Post
Fellowshi p Training								
Experienc e Post Fellowshi p								

complete the corresponding pathway section below):
☐ The transplant nephrology fellowship pathway , as described in <i>Section 66A</i> . <i>Transplant</i>
Nephrology Fellowship Pathway below. ☐ The clinical experience pathway, as described in Section 66B. Clinical Experience Pathway
below.
☐ The 3 year pediatric nephrology fellowship pathway , as described in <i>Section 66A</i> . Three-year
Pediatric Nephrology Fellowship Pathway below. The 12-month pediatric transplant nephrology fellowship pathway , as described in Section
66B. Twelve-month Pediatric Transplant Nephrology Fellowship Pathway below.
☐ The combined pediatric nephrology training and experience pathway, as described in
Section 66C. Combined Pediatric Nephrology Training and Experience Pathway below. The conditional approval pathway, as described in Section 6F: Conditional Approval for
Primary Transplant Physician below, if the primary kidney transplant physician changes at an approved kidney transplant program.

5. Which of the following pathways is the proposed primary physician applying (check one, and

6A. 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.

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 primary transplant physician.

- During the fellowship period, 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 a log that includes each evaluation date and the signature of the director of the training program or the primary transplant physician.
- 3. 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 a log that includes each evaluation date and the potential living kidney donor's medical record number or other unique identifier, and the signature of the director of the training program or the primary transplant physician.

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.
	☐ The physician has experience with histocompatibility and tissue typing.

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 a log that includes the date of procurement, donor type, and Donor ID.

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

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

- 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
 - 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.

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

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6B. 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:

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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 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 transplant program.

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

- 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 a log that includes each evaluation date and the signature of the program director, division Chief, or department Chair from the program where the physician gained this experience.
- 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 a log that includes each evaluation date and the potential living kidney donor's medical record number or other unique identifier, and the signature of the program director, division Chief, or department Chair from the program where the physician gained this experience.

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 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.
	\Box 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.

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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 a log that includes the date of procurement, donor type, and Donor ID.

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

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

7. Provide the following letters with the application:

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- 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,
 - 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 kidney transplantation.

6C. 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:

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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.

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 primary transplant physician.

- 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.
- 3. During the fellowship period 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 a log that includes each evaluation date and the signature of the director of the training program or the primary transplant physician.
- 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
 The physician has experience managing pediatric patients with end-stage renal disease.
 The physician has experience with the selection of appropriate pediatric recipients for transplantation.
 The physician has experience with donor selection.
 The physician has experience with histocompatibility and tissue typing.
 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

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	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?
	☐ 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.

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

- 6. The physician has observed at least 3 kidney transplants involving a pediatric recipient. This experience must be documented on a log that includes the transplant date, recipient age/date of birth, and medical record number or other unique identifier.
- 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,
 - 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.

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

6D. 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:

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- 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 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 primary transplant physician.

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.

This experience must be documented on a log that includes each evaluation date and the signature of the director of the training program or the primary transplant physician.

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.
	\Box The physician has experience with fluid and electrolyte management.

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□ 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.
□ The physician has experience with differential diagnosis of renal dysfunction in the allograft recipient.
□ 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.
□ 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.

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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 a log that includes the date of procurement, donor type, and Donor ID.

- 6. The physician has observed at least 3 kidney transplants involving a pediatric recipient.

 This experience must be documented on a log that includes the transplant date, recipient age/date of birth, and medical record number or other unique identifier.
- 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,
 - 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.

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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.

6E. Combined Pediatric Nephrology Training and Experience Pathway

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

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- 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.
- 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 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 primary transplant physician.
- 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 a log that includes each evaluation date and the signature of the program director, division Chief, or department Chair from the program
- 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>.

 Check all that apply

where the physician gained this experience.

\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.
\Box The physician has experience with fluid and electrolyte management.

Department of Health and Human Services OMB No. 0915-0184 Health Resources and Services Administration Expiration Date: 08/31/2023 ☐ 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. ☐ The physician has experience with long-term outpatient care of pediatric allograft

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

including antibiotics, in the pediatric patient.

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.

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

- 7. The physician has observed at least 3 kidney transplants involving a pediatric recipient.

 This experience must be documented on a log that includes the transplant date, recipient age/date of birth, and medical record number or other unique identifier.
- 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,
 - 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

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

program previously served by the physician, at its discretion.

6F. 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:

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- 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 a log that includes the date of transplant and medical record number or other unique identifier, and the signature of the program director, division Chief, or department Chair from the program where the physician gained this experience.
- 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 a log that includes each evaluation date and the signature of the program director, division Chief, or department Chair from the program where the physician gained this experience.
- 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 a log that includes each evaluation date and the potential living kidney donor's medical record number or other unique identifier, and the signature of the program director, division Chief, or department Chair from the program where the physician gained this experience.

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.
	\square The physician has experience with immediate postoperative patient care.
	$\hfill \square$ 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.
	\Box The physician has experience with interpretation of ancillary tests for renal dysfunction.

\Box The physician has experience with long term outpatient care.	
If a box is not checked, please provide an explanation:	

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- 5. The physician has **12 months experience** on an active kidney transplant service as the primary kidney transplant physician or under the direct supervision of a qualified kidney transplant physician and in conjunction with a kidney transplant surgeon at a designated kidney transplant program. These 12 months of experience must be acquired within a 2-year period.
- 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 a log that includes the date of procurement, donor type, and Donor ID.
- 7. The physician has observed **at least 3** kidney transplants.

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

- 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,
- 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 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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	Assessment):	
	Name	NPI #
2.	Check yes or no for each of the following. Provide d	locumentation where applicable:
Yes No		
	2a. Does the surgeon have an M.D., D.O., or equive current license to practice medicine in the hospital's sometime a copy of the surgeon's resume/CV.	,
	2b. Has the surgeon been accepted onto the hospital's hospital?	medical staff, and is practicing on site at this
	Provide documentation from the hospital credent surgeon's state license, board certification, traineducation, and that the surgeon is currently a medical staff.	ning, and transplant continuing medical
3.	Certification. Check one and provide corresponding	documentation:
	3a. The surgeon is currently certified by the American Urology, the American Board of Osteopathic Surgery Surgeons of Canada.	•
	Provide a copy of the surgeon's current board certif	īcation.
	3b. The surgeon has just completed training and is performed of Urology. Therefore, the program is requesting consurgeon time to complete board certification, with the 16-month period.	ditional approval for 16 months to allow the
	Provide documentation supporting that training ha	s been completed and certification is
	pending, which must include the anticipated date o	f board certification and where the surgeon
	is in the process to be certified.	
	3c. The surgeon is without certification by the Americ Urology, the American Board of Osteopathic Surgery Surgeons of Canada. If this option is selected:	<u> </u>
	 The surgeon must be ineligible for American I why the individual is ineligible: 	board certification. Provide an explanation

- 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,
 - 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:

	Approve d Fellowsh		nte M/ ′YY)					# of Kidney
Training and Experienc e	ip Program ? Y/N	Star t	End	Transplan t Hospital	Program Director	# Kidney Transplan ts as Primary	# Kidney Transplan ts as 1st Assistant	Procureme nts as Primary or 1 st Assistant
Fellowshi p Training								
Experienc e Post Fellowshi p								

5.	Which of the following pathways is the proposed primary surgeon applying (check one, and complete the corresponding pathway section below):
	☐ The fellowship pathway , as described in <i>Section 55A</i> . Formal 2-year Transplant Fellowship Pathway below.
	☐ The clinical experience pathway , as described in <i>Section 55B. Clinical Experience Pathway</i> below.

6. Pediatric-Specific Requirements

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a. The surgeon has performed at least 10 kidney transplants, as the primary surgeon or first assistant, in recipients less than 18 years old at the time of transplant. At least 3 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. This experience must be documented on a log that includes the date of transplant, the recipient's date of birth, the recipient's weight at transplant if less than 25 kilograms, and medical record number or other unique identifier.

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b.	The surgeon has maintained a current working knowledge of pediatric kidney
	transplantation, defined as direct involvement in pediatric kidney transplant patient
	care <u>within the last 2 years</u> .
	Check all that apply
	\Box The surgeon has experience with managing pediatric patients with end stage
	renal disease.
	\Box The surgeon has experience with the selection of appropriate pediatric recipients
	for transplantation.
	\square The surgeon has experience with donor selection.
	☐ The surgeon has experience with HLA typing.
	\square The surgeon has experience with performing the transplant operation.
	☐ 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.
	\Box The surgeon has experience with histological interpretation of allograft biopsies.
	☐ 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:

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 a log that includes the date of transplant, role of the surgeon, medical record number or other unique identifier, and the fellowship director's signature.

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 a log that includes the date of procurement, Donor ID.

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 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.
	\Box The surgeon has experience with performing the transplant operation.
	\Box 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.
	\Box The surgeon has experience with histological interpretation of allograft biopsies.
	\Box 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:

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- 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,
 - 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.

• 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:

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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 a log that includes the date of transplant, the role of the surgeon, and medical record number or other unique identifier.

2. The surgeon has performed **at least 15** kidney procurements as primary surgeon, cosurgeon, 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.

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

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?
	☐ Does the surgeon have experience with donor selection?
	☐ 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
	allograft recipient?
	\Box Does the surgeon have experience with histological interpretation of allograft biopsies?
	\square Does the surgeon have experience with interpretation of ancillary tests for renal
	dysfunction?

 \square Does the surgeon have experience with long term outpatient care?

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

4. Provide the following letters along with the application:

- 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 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,
 - 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.

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

Part 7B: Primary Pediatric Kidney Transplant Physician Requirements

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1.	Name of Proposed Primary Pediatric Kidney Transpla Assessment):	nt Physician (as indicated in Certificate of
	Name	NPI #
2.	Check yes or no for each of the following. Provide do	cumentation where applicable:
es No		
	2a. Does the physician have an M.D., D.O., or equivalent license to practice medicine in the hospital's start Provide a copy of the physician's resume/CV.	_
	2b. Has the physician been accepted onto the hospital' this hospital?	's medical staff, and is practicing on site at
	Provide documentation from the hospital credentic physician's state license, board certification, train education, and that the physician is currently a member medical staff.	ing, and transplant continuing medica
3.	Certification. Check one and provide corresponding of	locumentation:
	3a. The physician is currently certified in nephrology be the American Board of Pediatrics, or the Royal College Provide a copy of the physician's current board certification.	of Physicians and Surgeons of Canada.
	3b. The physician is without certification in nephro Medicine, the American Board of Pediatrics, or the Ro Canada. This option can only be utilized if pursuing the Three-ye	oyal College of Physicians and Surgeons of
	 The physician must be ineligible for American boo why the individual is ineligible: 	
	 Provide a plan for continuing education that is comaintenance of certification Provide at least 2 two letters of recommendation programs not employed by the applying hospital owhy an exception is reasonable, the individual's overall qualifications to act a othe individual's personal integrity and honest 	omparable to American board from directors of designated transplant that address s a primary kidney transplant physician,

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

Training	Approved Fellowshi					#Kidney Patients Followed		
and Experienc e	p Program? Y/N	Start	End	Transplant Hospital	Program Director	Pre	Peri	Post
Fellowshi p Training								
Experienc e Post Fellowshi p								

5.	Which of the following pathways is the proposed primary pediatric physician applying (check one, and complete the corresponding pathway section below):		
	☐ The 3-year pediatric nephrology fellowship pathway , as described in <i>Section 6A</i> . Three-year Pediatric Nephrology Fellowship Pathway below.		
	☐ The 12-month pediatric transplant nephrology fellowship pathway , as described in <i>Section</i>		
	6B. Twelve-month Pediatric Transplant Nephrology Fellowship Pathway below.		
	☐ The combined pediatric nephrology training and experience pathway , as described in Section 6C. Combined Pediatric Nephrology Training and Experience Pathway below.		

6A. 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:

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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.

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 primary transplant physician.

- 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.
- 3. During the fellowship period 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 a log that includes each evaluation date and the signature of the director of the training program or the primary transplant physician.

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

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	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.

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

- 6. The physician has observed at least 3 kidney transplants involving a pediatric recipient. This experience must be documented on a log that includes the transplant date, recipient age/date of birth, and medical record number or other unique identifier.
- 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,
 - 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.

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

6B. 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:

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- 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 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 primary transplant physician.

- 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.
 - This experience must be documented on a log that includes each evaluation date and the signature of the director of the training program or the primary transplant physician.
- 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
 The physician has experience managing pediatric patients with end-stage renal disease.
 The physician has experience with the selection of appropriate pediatric recipients for transplantation.
 The physician has experience with donor selection.
 The physician has experience with histocompatibility and tissue typing.
 The physician has experience with immediate post-operative care including those issues of management unique to the pediatric recipient.

 \Box The physician has experience with fluid and electrolyte management.

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□ 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.
□ The physician has experience with differential diagnosis of renal dysfunction in the allograft recipient.
□ 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.
□ 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.

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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 a log that includes the date of procurement, donor type, and Donor ID.

- 6. The physician has observed at least 3 kidney transplants involving a pediatric recipient. This experience must be documented on a log that includes the transplant date, recipient age/date of birth, and medical record number or other unique identifier.
- 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,
 - 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.

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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.

6C. Combined Pediatric Nephrology Training and Experience Pathway

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

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- 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.
- 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 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 primary transplant physician.
- 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 a log that includes each evaluation date and the signature of the program director, division Chief, or department Chair from the program
- 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>.

 Check all that apply

where the physician gained this experience.

\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.
\Box The physician has experience with fluid and electrolyte management.

Department of Health and Human Services OMB No. 0915-0184 Health Resources and Services Administration Expiration Date: 08/31/2023 ☐ 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. ☐ The physician has experience with long-term outpatient care of pediatric allograft

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

including antibiotics, in the pediatric patient.

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.

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

- 7. The physician has observed at least 3 kidney transplants involving a pediatric recipient.

 This experience must be documented on a log that includes the transplant date, recipient age/date of birth, and medical record number or other unique identifier.
- 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,
 - 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

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

program previously served by the physician, at its discretion.

Part 7C: Conditional Approval for a Pediatric Component

1.	Name of Proposed Primary Pediatric Kidney Trathe bylaw requirements:	ansplant Surgeon or Physician who fully meets
	Name	Proposed Position
	Name of Proposed Primary Pediatric Kidney Tr proposed as conditional personnel:	ansplant Surgeon or Physician who is being
	Name	Proposed Position

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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 7B: 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 Error: Reference source not found, 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 5*, Section 55A. Formal 2-year Transplant Fellowship Pathway
 - O The **kidney transplant program clinical experience pathway**, as described in application *Part 5*, *Section 55B. 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.
 - This experience must be documented on a log that includes the date of transplant, the recipient's date of birth, the recipient's weight at transplant if less than 25 kilograms, the role of the surgeon, and medical record number or other unique identifier.
 - The surgeon maintained a current working knowledge of pediatric kidney transplantation, defined as direct involvement in pediatric kidney transplant patient care

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 \times

in the last 2 years. This includes (check all that apply) \Box the management of pediatric patients with end stage renal disease \square the selection of appropriate pediatric recipients for transplantation \Box donor selection ☐ histocompatibility and HLA typing ☐ performing the pediatric transplant operation ☐ immediate postoperative and continuing inpatient care \Box the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression ☐ differential diagnosis of renal dysfunction in the allograft recipient ☐ histological interpretation of allograft biopsies ☐ interpretation of ancillary tests for renal dysfunction ☐ long term outpatient care Option B. The program has a qualified primary pediatric kidney surgeon who meets all of the requirements described in application Part 7A: Primary Pediatric Kidney Transplant Surgeon Requirements and a **physician** who meets all of the following requirements: 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. This experience must be documented on a log that includes the date of transplant, the medical record number or other unique identifier, and the signature of the training program director or the primary physician of the transplant program. The physician has maintained a current working knowledge of pediatric kidney transplantation, defined as direct involvement in kidney transplant patient care during the past 2 years. This includes (check all that apply) ☐ the management of pediatric patients with end-stage renal disease \Box the selection of appropriate pediatric recipients for transplantation ☐ donor selection ☐ histocompatibility and HLA typing immediate post-operative care including those issues of management unique to the pediatric recipient ☐ fluid and electrolyte management ☐ the use of immunosuppressive therapy in the pediatric recipients including sideeffects of drugs and complications of immunosuppression

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\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
☐ histological interpretation of allograft biopsies
☐ 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 should have 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. If the physician has completed these observations, they must be documented in a log that includes the date of transplant and/or procurement and Donor ID.
- Provide the following letters with the application:
 - O 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
 - 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.
 - O 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 ust also have the following:
-	estions 1 through 4, check to attest that the program has adequate resources in place for living kidney recovery:
1. Pro	otocols and Resources for Evaluations
	The kidney recovery hospital has protocols and resources in place for performing living donor evaluations.
2. Su	rgical Resources
	The kidney recovery hospital has surgical resources on site for open or laparoscopic living donor kidney recoveries.
3. Liv	ing 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. Liv	ing Donor Psychological Evaluation
	The kidney recovery hospital has the clinical resources to perform a psychosocial evaluation of the living donor.
5. In o	lependent 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):

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6. Primary Open Living Donor Kidney Surgeon

unique identifier.

A kidney donor surgeon who performs open living donor nephrectomies must be on site.					
Name of Proposed Open Living Donor Nephrectomies Surgeon:					
Name	 NPI #				
An open living donor nephrectomies must meet one	e of the following criteria.				
Check one and provide corresponding documentati	ion				
□ Completion of a formal 2-year surgical transplar program approved by the American Society of Trans Physicians and Surgeons of Canada, or other recognithe OPTN Contractor as described in Bylaw Section E Programs. Provide this surgeon's certificate of completion of a	plant Surgeons, the Royal College of ized fellowship training program accepted by E.4.A: Transplant Surgeon Fellowship Training				
☐ Completion of at least 10 open nephrectomies, in the removal of diseased kidneys, as primary surgeon these open nephrectomies must have been performed This experience must be documented on a log that surgeon, the type of procedure (open or laparoscopy).	n, co-surgeon, or first assistant. At least 5 of ed as the primary surgeon or co-surgeon. includes the date of recovery, role of the				

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:

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Name of Proposed Primary Laparoscopic Living Donor Kidney Surgeon:					
Name	 NPI #				
☐ The surgeon must have completed at least 15 as primary surgeon, co-surgeon, or first assistant. This experience must be documented on a log th surgeon, the type of procedure (open or laparose unique identifier.	at includes the date of recovery, role of the				
☐ Seven of these nephrectomies must have been and this role should be documented by a letter frod director, division chief, or department chair from experience.	om the fellowship program director, program				

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 paperwork@hrsa.gov.