OPTN Membership Application for Kidney Transplant Programs

OMB No. 0915-0184

Expiration Date: xx/xx/20xx

CERTIFICATION

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

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

	OPTN Representative	
Printed Name	Signature	Email Address

Department of Health and Human Services Health Resources and Services Administration OMB No. 0915-0184 Expiration Date: xx/xx/20xx

Part 1: General Information

Name of Transplant Hospital:				
OPTN Member Code (4 Letter	·s):			
Transplant Hospital Address (where transplants	s occur)		
Street:		Suite:		
City:	State:	Zip:		
Kidney Transplant Program P	hone #:			
Kidney Transplant Program Fa	ax #:			
Name of Person Completing F	Form:		Title:	
Email Address of Person Com	pleting Form:			
Date Form is submitted to OP	TN Contractor:			

Part 2: Certificate of Assessment

The hospital must conduct an assessment of all transplant program surgeons and physicians for any involvement in prior transgressions of OPTN obligations and plans to ensure compliance.

The **primary surgeon** and **primary physician** are responsible for ensuring the operation and compliance of the program according to the requirements set forth in the OPTN Bylaws. The transplant hospital must notify the OPTN Contractor immediately if at any time the program does not meet these requirements. The individuals reported to the OPTN Contractor as the program's primary surgeon and primary physician should be the same as those reported to the Center for Medicaid and Medicare Services (CMS).

Additional Transplant Surgeons must be credentialed by the transplant hospital to provide transplant services and be able to independently manage the care of transplant patients, including performing the transplant operations and organ procurement procedures.

Additional Transplant Physicians must be credentialed by the transplant hospital to provide transplant services and be able to independently manage the care of transplant patients.

A surgeon or physician employed by the transplant hospital that does not independently manage the care of transplant patients may be listed as **other**.

This information is subject to medical peer review confidentiality requirements and must be submitted according to the guidelines provided in the application.

Instructions:

On the next page, list all surgeons and physicians involved in the transplant program.

- Use the checkboxes to indicate if the individual is part of the main program, living donor component of the program, and/or the pediatric component of the program. Multiple boxes may be checked.
- For any surgeon or physician indicated as 'Primary' that isn't already the approved primary surgeon or primary physician for the program, complete the relevant sections of the application below.
- For each surgeon or physician that is newly designated as 'Additional', provide a credentialing letter with this application.
- For each surgeon or physician listed as 'Other', no further action is needed.
- If you have answered 'yes' to any surgeon or physician having prior transgressions with the OPTN, please explain in the blank space provided below the table.

Department of Health and Human Services Health Resources and Services Administration

OMB No. 0915-0184 Expiration Date: xx/xx/20xx

Name	NPI# (optional)	Surgeon or Physician	Primary, Additional, or Other	Main Program	Living Donor Component	Pediatric Component
Do any of the individuals					oliance:	

Do any of the individuals listed above have OPTN transgressions: \Box Yes \Box No	
If yes, provide the name of the individual(s) and the program's plan to ensure compliance:	

OMB No. 0915-0184

Expiration Date: xx/xx/20xx

Part 3: Program Coverage Plan

The program director, along with the primary surgeon and physician, must submit a detailed **Program Coverage Plan** to the OPTN Contactor. The Program Coverage Plan must describe how continuous medical and surgical coverage is provided by transplant surgeons and physicians who have been credentialed by the transplant hospital to provide transplant services to the program.

A transplant program must inform its patients if it is staffed by a single surgeon or physician and acknowledge the potential unavailability of these individuals, which could affect patient care, including the ability to accept organ offers, procurement, and transplantation.

Instructions:

Surgeons

Complete the questions below and provide documentation where applicable.

Transplant Surgeon and Physician Coverage

Juige	.013
Yes N	0
	Is this a single surgeon program?
	If yes, provide a copy of the patient notice or protocol for providing patient notification.
	Does the transplant program have transplant surgeons available 365 days a year, 24 hours a day, 7 days a week to provide program coverage?
	If the answer is no, provide a written explanation in the Program Coverage Plan that justifies the current level of coverage.
	Is a transplant surgeon readily available in a timely manner to facilitate organ acceptance, procurement, and transplantation?
	Will any of the transplant surgeons be on call simultaneously at two transplant programs more than 30 miles apart? If the answer is yes, the program must request an exemption from the MPSC to operate as a transplant program sharing primary personnel with another transplant hospital, without
	additional transplant staff.
	Is the primary transplant surgeon designated as the primary transplant surgeon at more than one
	transplant hospital?
	If yes, answer the question below.
	Yes No

Department of Health and Human Services Health Resources and Services Administration	OMB No. 0915-0184 Expiration Date: xx/xx/20xx
\Box \Box Do you have additional surgeons listed with the must request an exemption from the MPSC to optimary personnel with another transplant hospital	operate as a transplant program sharing
□ □ Is the primary transplant surgeon onsite full-time at th If the answer is no, please describe in detail the ons	ite arrangements:
□ □ Does the primary transplant surgeon have on-call re hospital at the same time? If the answer is yes, pleas	esponsibilities at more than one transplant se explain below:
Physicians Yes No	
☐ ☐ Is this a single physician program? If yes, provide a copy of the patient notice or protoco	ol for providing patient notification.
 □ Does the transplant program have transplant physician 7 days a week to provide program coverage? If the answer is no, provide a written explanation the 	
□ □ Will any of the transplant physicians be on call simulton than 30 miles apart? If the answer is yes, the program must request an expression transplant program sharing primary personnel wanditional transplant staff.	exemption from the MPSC to operate as a
 □ Is the primary transplant physician designated as the one transplant hospital? If yes, answer the question below. Yes No □ □ Do you have additional physicians listed with the If the answer is no, the program must request an transplant program sharing primary personnel wanditional transplant staff. 	ne program? exemption from the MPSC to operate as a
☐ ☐ Is the primary transplant physician onsite full-time at t If the answer is no, please describe in detail the ons	

Department of Health and Human Services	OMB No. 0915-0184
Health Resources and Services Administration	
□ □ Does the primary transplant physician have on-call res hospital at the same time? If the answer is yes, please explain below:	ponsibilities at more than one transplant
Patient Notification	
Check the box below to attest to the following:	
☐ The transplant program provides patients with a written when placed on the waiting list and when there are any personnel.	,

Attach a copy of the Program Coverage Plan to the application.

Part 4: 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.

Program Director(s) (list all):				
Name	Credentials			
Name	Credentials			
Name	Credentials			
Name				

Part 5: Primary Kidney Transplant Surgeon Requirements

OMB No. 0915-0184

	Name of Proposed Primary Kidney Transplant Surgeon (as Assessment):	indicated in Part 2: Certificate o
	Name	NPI # (optional)
Ch	Check to attest to each of the following. Provide documenta	tion where applicable:
	☐ The surgeon has an M.D., D.O., or equivalent degree fro license to practice medicine in the hospital's state or juris	
	Provide a copy of the surgeon's medical license or requirement.	resume/CV to show proof of this
	☐ The surgeon has been accepted onto the hospital's medithis hospital.	ical staff and is practicing on site a
	Provide documentation from the hospital credentialing surgeon's state license, board certification, training, and that the surgeon is currently a member medical staff.	and transplant continuing medica
Ce	Certification. Check one and provide corresponding docume	ntation:
	☐ The surgeon is currently certified by the American Board Urology, the American Board of Osteopathic Surgery, or Surgeons of Canada.	- •
	Provide a copy of the surgeon's current board certificat	ion.
	The surgeon has just completed training and is pending of Urology. Therefore, the program is requesting concallow the surgeon time to complete urology board crenewal for one additional 16-month period.	litional approval for 16 months to
	Provide documentation supporting that training has be certification is pending, which must include the anticand where the surgeon is in the process to be certified.	-
	☐ The surgeon is without certification by the American Boo of Urology, the American Board of Osteopathic Surgery and Surgeons of Canada or pending certification by the A If this option is selected:	, or the Royal College of Physicians

Pathway below.

below.

OMB No. 0915-0184 Expiration Date: xx/xx/20xx

	ехріапатіоі 	n wny tne ina 	lividual is ineligible: 	
•	maintenance o the surgeredits. o the surgeredits every the written the mate o the transplant o why are	geon obtains geon performs geon performs geon performs gere years, wi gor electronic gerial in the CN gsplant hospita least 2 two grograms not greyennis	ion. This plan must at least req 60 hours of Category I contin s a self-assessment that is releve ith a score of 75% or higher. S question-and-answer exercise ME program. al document completion of this to letters of recommendation t employed by the applying hos reasonable.	uing medical education (CME) vant to the individual's practice Self-assessment is defined as a that assesses understanding of s continuing education. from directors of designated
4. Summa	o the sur adherii o any oth	rgeon's persoi ng to OPTN ok her matters ju	-	niliarity with and experience in ocols.
	o the sur adherii o any oth rize the surg	rgeon's persoi ng to OPTN ok her matters ju	nal integrity, honesty, and fan bligations and compliance prot Idged appropriate. g and experience in transplant:	niliarity with and experience in ocols.
	o the sur adherii o any oth rize the surg	geon's persoing to OPTN ob her matters ju geon's training	nal integrity, honesty, and fan bligations and compliance prot adged appropriate.	niliarity with and experience in ocols.
Training and	o the sur adherii o any oth rize the surg Da (MM/I	geon's person ng to OPTN ob her matters ju geon's training ate DD/YY)	nal integrity, honesty, and fan bligations and compliance prot Idged appropriate. g and experience in transplant:	niliarity with and experience in ocols.

☐ The **fellowship pathway**, as described in Section 55A. Formal 2-year Transplant Fellowship

☐ The clinical experience pathway, as described in Section 55B. Clinical Experience Pathway

5A.

tes and Services Administration Expiration Date: xx/xx/20xx

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:

OMB No. 0915-0184

- 1. The surgeon performed **at least 30** kidney transplants as the primary surgeon or first assistant during the 2-year fellowship period.
 - These transplants must be documented in the surgeon's fellowship operative log. The date of transplant, the role of the surgeon in the procedure, the medical record number or other unique identifier that can be verified by the OPTN Contractor, and the fellowship director's signature must be provided with this log.
- 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.

These procedures must be documented in the surgeon's fellowship operative log. The date of procurement and Donor ID must be provided with this log.

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 to attest to the following
	\square The surgeon has experience with managing patients with end stage renal disease.
	☐ 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.
	\Box 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.
4.	Check to attest to the following

☐ This training was completed at a hospital with a kidney transplant training program approved by the American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or another recognized surgical fellowship training program accepted by the OPTN Contractor as described in the Section E.4: Approved

Kidney Transplant Surgeon and Physician Fellowship Training Programs in the OPTN bylaws.

5. Provide the following letters with the application:

- A letter from the director of the training program and chair of the department or hospital credentialing committee verifying that the surgeon has met the above requirements and is qualified to direct a kidney transplant program.
- A letter of recommendation from the fellowship training program's primary surgeon and transplant program director outlining:
 - o the surgeon's overall qualifications to act as primary transplant surgeon.
 - o the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
 - o any other matters judged appropriate.

The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.

• A letter from the surgeon that details the training and experience 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:

OMB No. 0915-0184

Expiration Date: xx/xx/20xx

1. 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. This experience must be documented on a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. The log should be signed by the program director, division chief, or department chair from the program where the experience was gained.

<u>Note:</u> 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.

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 to attest to the following
	\Box The surgeon has experience with managing patients with end stage renal disease.

The surgeon has experience with managing patients with end stage renal disease.
The surgeon has experience with the selection of appropriate recipients for
transplantation.
The surgeon has experience with donor selection.
The surgeon has experience with histocompatibility and tissue typing.
The surgeon has experience with performing the transplant operation.
The surgeon has experience with immediate postoperative and continuing inpatient care.
The surgeon has experience with the use of immunosuppressive therapy including side
effects of the drugs and complications of immunosuppression.
The surgeon has experience with differential diagnosis of renal dysfunction in the
allograft recipient.
The surgeon has experience with histological interpretation of allograft biopsies.
The surgeon has experience with interpretation of ancillary tests for renal dysfunction.
The surgeon has experience with long term outpatient care.

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 surgeon's overall qualifications to act as primary transplant surgeon.
 - o the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
 - o any other matters judged appropriate.

The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.

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

Part 6: Primary Kidney Transplant Physician Requirements

OMB No. 0915-0184

	Name	NPI # (optional)
Ch	eck to attest to each of the following. Provide doc	umentation where applicable:
	The physician has an M.D., D.O., or equivalent d license to practice medicine in the hospital's stat	
	Provide a copy of the physician's medical lice requirement.	ense or resume/CV to show proof of thi
	The physician has been accepted onto the hospi at this hospital.	tal's medical staff, and is practicing on sit
	Provide documentation from the hospital crede physician's state license, board certification, treducation, and that the physician is currently a medical staff.	aining, and transplant continuing medica
Cei	tification. Check one and provide corresponding o	documentation:
	The physician is currently certified in nephro Medicine, the American Board of Pediatrics, or the	
		ne Royal College of Physicians and Surgeon
	Medicine, the American Board of Pediatrics, or the of Canada. Provide a copy of the physician's current board The physician is without certification in nephromatory Medicine, the American Board of Pediatrics, or the of Canada.	ne Royal College of Physicians and Surgeons certification. ology by the American Board of Internate ne Royal College of Physicians and Surgeons
	Medicine, the American Board of Pediatrics, or the of Canada. Provide a copy of the physician's current board The physician is without certification in nephromatory medicine, the American Board of Pediatrics, or the control of th	ne Royal College of Physicians and Surgeon. certification. cology by the American Board of Internative Royal College of Physicians and Surgeon. I therefore this option may not be used. In board certification. Provide an

5.

defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program.

OMB No. 0915-0184

- o the transplant hospital document completion of this continuing education.
- Provide at least 2 two letters of recommendation from directors of designated transplant programs not employed by the applying hospital that address:
 - o why an exception is reasonable.
 - O The physician's overall qualifications to act as a primary kidney transplant physician.
 - o the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
 - o any other matters judged appropriate.
- 4. Summarize the physician's training and experience in transplant:

Training and	Date (MM/DD/YY)		Transplant Hospital	Program Director		
Experience	Start	End	Transplant Hospital	110graill Director		
Fellowship						
Experience Post Fellowship						

Which of the following pathways is the proposed primary physician applying? (check one, and complete the corresponding pathway section below):
☐ The transplant nephrology fellowship pathway , as described in <i>Section 55A</i> . <i>Transplant Nephrology Fellowship Pathway</i> below.
☐ The clinical experience pathway, as described in Section 55B. Clinical Experience Pathway
below.
☐ The 3 year pediatric nephrology fellowship pathway, as described in Section 5Error:
Reference source not found below.
☐ The 12-month pediatric transplant nephrology fellowship pathway , as described in <i>Section</i>
5Error: Reference source not found below.
\square The combined pediatric nephrology training and experience pathway, as described in
Section 5Error: Reference source not found below.
\square The conditional approval pathway, as described in Section 5F: Conditional Approval for
Primary Transplant Physician below.

5A. Transplant Nephrology Fellowship Pathway

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

OMB No. 0915-0184

Expiration Date: xx/xx/20xx

1. Check to attest to the following

- ☐ 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.
- 2. 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 that can be verified by the OPTN, 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** 25 potential kidney recipients, including participation in selection committee meetings.

 This experience must be documented on a log that includes the each evaluation date and the signature of the director of the training program or the primary transplant physician.
- 4. 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 that can be verified by the OPTN, and the signature of the director of the training program or the primary transplant physician.

5.	The physician has maintained a current working knowledge of kidney transplantation,
	defined as direct involvement in kidney transplant care <u>in the last 2 years</u> .
	Check to attest to the following
	\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.

Department of Health and Human Services OMB No. 0915-0184 Health Resources and Services Administration Expiration Date: xx/xx/20xx ☐ 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. ☐ The physician has experience with the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression. ☐ The physician has experience with differential diagnosis of renal dysfunction in the allograft recipient. ☐ 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. 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 that can be verified by the OPTN. 8. 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 physician's overall qualifications to act as primary transplant physician. o the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols. o any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion. A letter from the physician that details the training and experience the physician has gained in kidney transplantation.

☐ This physician's training was completed at a hospital with a recognized fellowship training program accepted by the OPTN Contractor as described in the Section E.4:

9. Check to attest to the following

Expiration Date: xx/xx/20xx

OMB No. 0915-0184

Approved Kidney Transplant Surgeon and Physician Fellowship Training Programs in the OPTN bylaws.

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

5B. Clinical Experience Pathway

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

OMB No. 0915-0184

Expiration Date: xx/xx/20xx

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 that can be verified by the OPTN.

- 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 that can be verified by the OPTN, 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 to attest to the following

The physician has experience with managing patients with end stage renal disease.
The physician has experience with the selection of appropriate 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 postoperative patient care.
The physician has experience with the use of immunosuppressive therapy including side
effects of the drugs and complications of immunosuppression.
The physician has experience with differential diagnosis of renal dysfunction in the
allograft recipient.
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.

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 that can be verified by the OPTN.

7. Provide the following letters with the application:

- A letter from the qualified transplant physician or the kidney transplant surgeon who
 has been directly involved with the proposed physician documenting the physician's
 experience and competence.
- A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining:
 - 0 the physician's overall qualifications to act as primary transplant physician.
 - o the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
 - o any other matters judged appropriate.

The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.

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

5C. Three-year Pediatric Nephrology Fellowship Pathway

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

OMB No. 0915-0184

Expiration Date: xx/xx/20xx

Check to attest to the following

☐ This physician's training meets the requirements described abo	above
--	-------

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 that can be verified by the OPTN, 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 the 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 <u>over the last 2 years</u>.

Check to attest to the following

CII	eck to attest to the following
	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.

Department of Health and Human Services Health Resources and Services Administration

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,

OMB No. 0915-0184

Expiration Date: xx/xx/20xx

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 that can be verified by the OPTN.

7. Provide the following letters with the application:

including antibiotics, in the pediatric patient.

- 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 physician's overall qualifications to act as primary transplant physician.
 - o the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
 - o any other matters judged appropriate.

The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.

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

5D. Twelve-month Pediatric Transplant Nephrology Fellowship Pathway

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

OMB No. 0915-0184

Expiration Date: xx/xx/20xx

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 that can be verified by the OPTN, and the signature of the director of the training program or the primary transplant physician.

3. Check to attest to the following

- ☐ The experience in caring for pediatric patients occurred at a kidney transplant program with a qualified kidney transplant physician and surgeon that performs an average of at least 10 pediatric kidney transplants a year.
- 4. 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 the each evaluation date and the signature of the director of the training program or the primary transplant physician.

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

Department of Health and Human Services

OMB No. 0915-0184 Health Resources and Services Administration Expiration Date: xx/xx/20xx

	The physician has experience with immediate post-operative care including those issues
ш	
	of management unique to the pediatric recipient.
	The physician has experience with fluid and electrolyte management.
	The physician has experience with the use of immunosuppressive therapy in the pediatric
	recipient including side-effects of drugs and complications of immunosuppression, the
	effects of transplantation and immunosuppressive agents on growth and development.
	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.

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 that can be verified by the OPTN.

8. 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 physician's overall qualifications to act as primary transplant physician.
 - o the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
 - o any other matters judged appropriate.

The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.

Department of Health and Human Services Health Resources and Services Administration

OMB No. 0915-0184
Expiration Date: xx/xx/20xx

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

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

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

OMB No. 0915-0184

Expiration Date: xx/xx/20xx

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.	Check	to a	ttest	to	the	fol	lowi	ng
----	-------	------	-------	----	-----	-----	------	----

- ☐ 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 that can be verified by the OPTN, 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 where the physician gained this experience.
- 5. The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care over the last 2 years.

Cn	Check to attest to the following		
	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.		

Department of Health and Human Services Health Resources and Services Administration

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.

OMB No. 0915-0184

Expiration Date: xx/xx/20xx

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 that can be verified by the OPTN.

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 physician's overall qualifications to act as primary transplant physician.
 - o the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
 - o any other matters judged appropriate.

The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.

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

5F. Conditional Approval for Primary Transplant Physician

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

OMB No. 0915-0184

Expiration Date: xx/xx/20xx

- 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 that can be verified by the OPTN, 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 that can be verified by the OPTN, 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 to attest to the following □ The physician has experience with managing patients with end stage renal disease. □ The physician has experience with the selection of appropriate 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 postoperative patient care. □ The physician has experience with the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression. □ The physician has experience with differential diagnosis of renal dysfunction in the allograft recipient. □ The physician has experience with histological interpretation of allograft biopsies.

 \square The physician has experience with interpretation of ancillary tests for renal dysfunction.

☐ The physician has experience with long term outpatient care.

5. Check to attest to the following

- ☐ 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 that can be verified by the OPTN.
- 8. **Provide documentation** that the program has established and documented a **consulting relationship** with counterparts at another kidney transplant program.
- 9. 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 physician's overall qualifications to act as primary transplant physician.
 - o the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
 - o any other matters judged appropriate.

The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.

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

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.

Instructions for Pediatric Component:

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

- If the surgeon is already the approved primary surgeon of the kidney transplant program, complete numbers 1 and 3.
- If the surgeon is **NOT** already the approved primary surgeon of the kidney transplant program, complete numbers **1**, **2**, **and 3**. To demonstrate that the proposed surgeon meets the requirements in the bylaws for the main program as well as the pediatric component, check the box in number 2 to identify the desired pathway and complete the corresponding section of Part 5 of the kidney application.

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

• Indicate the pathway in Number 2 and complete the corresponding section in Part 6 of the application.

To apply for **conditional approval of a pediatric component**, complete section 7C of this application.

- For conditional approval, either the proposed primary surgeon or physician must be fully approved per the bylaws.
 - O Select **Option A** if the program has a qualified primary pediatric kidney **physician** who meets all of the requirements but the **surgeon** is seeking approval conditionally.
 - O Select **Option B** if the program has a qualified primary pediatric kidney **surgeon** who meets all of the requirements but the **physician** is seeking approval conditionally.

Part 7A: Primary Pediatric Kidney Transplant Surgeon Requirements

OMB No. 0915-0184

	Name	NPI # (optional)
	hich of the following pathways is the propos emplete the corresponding pathway section in	
	The fellowship pathway , as described in <i>Sec</i> Pathway in Part 5: Primary Kidney Transplan The clinical experience pathway , as described Part 5: Primary Kidney Transplant Surgeon R	t Surgeon Requirements above. I in Section 55B. Clinical Experience Pathway in
Pe	ediatric-Specific Requirements	
a.	assistant, in recipients less than 18 years old kidney transplants must have been in recipie 25 kilograms at the time of transplant. These or after fellowship, or across both periods. This experience must be documented on a	ey transplants, as the primary surgeon or first d at the time of transplant. At least 3 of these ents less than 6 years old or weighing less than e transplants must have been performed during log that includes the date of transplant, the ent at transplant if less than 25 kilograms, and tifier that can be verified by the OPTN.
b.	-	knowledge of pediatric kidney transplantation, Iney transplant patient care within the last 2
	· · · · · · · · · · · · · · · · · · ·	iging pediatric patients with end stage rena
	☐ The surgeon has experience with the se transplantation.	lection of appropriate pediatric recipients for
	☐ The surgeon has experience with donor sele☐ The surgeon has experience with HLA typin	
	 ☐ The surgeon has experience with performing ☐ The surgeon has experience with immediat ☐ The surgeon has experience with the use of 	e postoperative and continuing inpatient care. immunosuppressive therapy including side
	effects of the drugs and complications of in The surgeon has experience with differenting recipient.	mmunosuppression. al diagnosis of renal dysfunction in the allografi
	 ☐ The surgeon has experience with histologic ☐ The surgeon has experience with interpreto ☐ The surgeon has experience with long term 	tion of ancillary tests for renal dysfunction.

Part 7B: Primary Pediatric Kidney Transplant Physician Requirements

OMB No. 0915-0184

1.	Name of Proposed Primary Pediatric Kidney Transplant Physician (as Indicated in Part 2: Certificate of Assessment):	
	Name NPI # (optional)	
2.	Which of the following pathways is the proposed primary pediatric physician applying (check one, and complete the corresponding pathway section in Part 6 of this application):	
	☐ The 3-year pediatric nephrology fellowship pathway , as described in <i>Section Error</i> : Reference source not found in Part 6: Primary Kidney Transplant Physician Requirements above.	
	☐ The 12-month pediatric transplant nephrology fellowship pathway, as described in Section Error: Reference source not found in Part 6: Primary Kidney Transplant Physician Requirements above.	
	☐ The combined pediatric nephrology training and experience pathway, as described in Section Error: Reference source not found in Part 6: Primary Kidney Transplant Physician Requirements above	

Part 7C: Conditional Approval for a Pediatric Component

Instructions: Check Option A or Option B and complete the corresponding portions of the application. Provide supporting documentation where applicable.

OMB No. 0915-0184

Option A. The program has a qualified primary pediatric kid requirements described in Part 7B: Primary Pediatric Kidner above and a surgeon who meets all of the following requirements.		uirements described in Part 7B: Primary Pediatric	Kidney Transplant Physician Requirements
	1. Name of proposed primary pediatric kidney trans requirements:		plant surgeon who meets conditional bylaw
		Name	NPI # (optional)

- 2. 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 Section 55A. Formal 2-year Transplant Fellowship Pathway in Part 5: Primary Kidney Transplant Surgeon Requirements of the application above.
 - O The kidney transplant program clinical experience pathway, as described in *Section 55B*. *Clinical Experience Pathway* in Part 5: Primary Kidney Transplant Surgeon Requirements of the application above.
 - If the surgeon is not the approved primary transplant surgeon of the kidney program, complete the corresponding section in Part 5 of the kidney application for one of the pathways listed above.
- 3. 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 that can be verified by the OPTN Contractor.

4.	The surgeon maintained a current working knowledge of pediatric kidney transplantation defined as direct involvement in pediatric kidney transplant patient care <u>in the last 2 years</u> .
	Check to attest to the following
	\Box The surgeon has experience with the management of pediatric patients with end stage rena disease.
	\Box The surgeon has experience with the selection of appropriate pediatric recipients for transplantation.

Health Resources and Services Administration Expiration Date: xx/xx/20xx \square The surgeon has experience with donor selection. ☐ The surgeon has experience with histocompatibility and HLA typing. ☐ The surgeon has experience with performing the pediatric transplant operation. ☐ The surgeon has experience with immediate postoperative and continuing inpatient care. ☐ The surgeon has experience with the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression. \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. ☐ The surgeon has experience with interpretation of ancillary tests for renal dysfunction. \square The surgeon has experience with 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 above** and a **physician** who meets *all* of the following requirements: 1. Name of proposed primary pediatric kidney transplant physician who meets conditional bylaw requirements: Name NPI # (optional) 2. 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 or documentation demonstrating approval to take the American Board of Pediatrics exam. 3. Check to attest to the following ☐ The physician gained a **minimum of 2 years of experience** during or after fellowship, or accumulated during both periods, at a kidney transplant program. 4. 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 that can be verified by the OPTN Contractor, and the signature of the training program director or the primary physician of the transplant program. 5. 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. Check to attest to the following ☐ The physician has experience managing pediatric patients with end-stage renal disease.

OMB No. 0915-0184

Department of Health and Human Services

Department of Health and Human Services OMB No. 0915-0184 Health Resources and Services Administration Expiration Date: xx/xx/20xx ☐ The physician has experience managing the selection of appropriate pediatric recipients for transplantation. \square The physician has experience with donor selection. ☐ The physician has experience with histocompatibility and HLA typing. ☐ The physician has experience managing 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 recipients including side-effects of drugs and complications of immunosuppression. \square The physician has experience with 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.

 \Box The physician has experience with the histological interpretation of allograft biopsies.

 \Box 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.

6. 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

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.

7. 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.
- O A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining:
 - the physician's overall qualifications to act as a primary transplant physician,
 - the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations.
 - any other matters judged appropriate.

The MPSC may request additional recommendation letters from the primary 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.

Part 8: Kidney Transplant Programs that Perform Living Donor Recovery

OMB No. 0915-0184

Expiration Date: xx/xx/20xx

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

Kidney recovery hospitals must meet all the requirements of a designated kidney transplant program

and	d must also have the following:	
For questions 1 through 4, check to attest that the program has adequate resources in place for living donor kidney recovery:		
1.	Protocols and Resources for Evaluations	
	☐ The kidney recovery hospital has protocols and resources in place for performing living donor evaluations.	
2.	Surgical Resources	
	☐ The kidney recovery hospital has surgical resources on site for open or laparoscopic living donor kidney recoveries.	
	te: Some pediatric living donor or kidney paired donation transplants may require that the living an donation occurs at a hospital that is separate from the approved transplant hospital.	
3.	Living 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.	Living Donor Psychological Evaluation	
	☐ The kidney recovery hospital has the clinical resources to perform a psychosocial evaluation of the living donor.	
5.	Independent 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):	

6.

7.

the following criteria:

Primary Open Living Donor Kidney Surgeon		
Name of Proposed Open Living Donor Nephrectomies Surgeon (as indicated in Part 2: Certificate of Assessment):		
Name	NPI # (optional)	
	A kidney donor surgeon who performs open living donor nephrectomies must be on site. An open living donor nephrectomies surgeon must meet <i>one</i> of the following criteria:	
Check one and provide corresponding documentati	ion	
approved by the American Society of Transplar Surgeons of Canada, or other recognized fello Contractor as described in Bylaw Section E Programs.	ant fellowship in kidney at a fellowship program at Surgeons, the Royal College of Physicians and whip training program accepted by the OPTN E.4.A: Transplant Surgeon Fellowship Training	
Provide this surgeon's certificate of completion	of an approved fellowship in kidney.	
removal of diseased kidneys, as primary surge these open nephrectomies must have been perfo This experience must be documented on a log	that includes the date of recovery, role of the roscopic), and medical record number or other	
Primary Laparoscopic Living Donor Kidney Surgeon		
Name of Proposed Primary Laparoscopic Living I Certificate of Assessment):	Donor Kidney Surgeon (as indicated in Part 2:	
Name	NPI # (optional)	

A surgeon who performs laparoscopic living donor kidney recoveries must be on site and must meet

OMB No. 0915-0184

Department of Health and Human Services Health Resources and Services Administration The surgeon must have completed at least 15 laparoscopic nephrectomies in the last 5 years as primary surgeon, co-surgeon, or first assistant. This experience must be documented on a log that includes the date of recovery, role of the surgeon, the type of procedure (open or laparoscopic), and medical record number or other unique identifier that can be verified by the OPTN Contractor. Seven (7) of these nephrectomies must have been performed as primary surgeon or co-surgeon, and this role should be documented by a letter from the fellowship program director, program director, division chief, or department chair from the program where the surgeon gained this

8. Kidney Paired Donation (KPD)

experience.

Transplant hospitals that choose to participate in the OPTN KPD program must do all of the following:

- a. Meet all the requirements of **Part 8: Kidney Transplant Programs that Perform Living Donor Recovery** above.
- b. Notify the OPTN in writing if the transplant hospital decides to participate in the OPTN KPD program. A transplant hospital must notify the OPTN in writing if it decides to quit its participation in the OPTN KPD program.
- c. Provide to the OPTN a primary KPD contact that is available to facilitate the KPD match offer and transplant, and provide at least one alternate KPD contact that is a member of the hospital's staff and can fulfill the responsibilities required by policy.
 - Complete the form Kidney Paired Donation Match Offer Support any time there is a change to the program's KPD contacts.

PUBLIC BURDEN STATEMENT

OMB No. 0915-0184

Expiration Date: xx/xx/20xx

The private, non-profit Organ Procurement and Transplantation Network (OPTN) collects this information in order to perform the following OPTN functions: to assess whether applicants meet OPTN Bylaw requirements for membership in the OPTN; and to monitor compliance of member organizations with OPTN Obligations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0915-0184 and it is valid until xx/xx/xxxx. 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 8 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.