

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.

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
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Part 1: General Information

Name of Transplant Hospital: _____

OPTN Member Code (4 Letters): _____

Transplant Hospital Address (where transplants occur)

Street: _____ Suite: _____

City: _____ State: _____ Zip: _____

Kidney Transplant Program Phone #: _____

Kidney Transplant Program Fax #: _____

Name of Person Completing Form: _____ Title: _____

Email Address of Person Completing Form: _____

Date Form is submitted to OPTN Contractor: _____

Part 2: Certificate of Assessment

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

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

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

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

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

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

Instructions:

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

- *Use the checkboxes to indicate if the individual is part of the main program, 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.*

<i>Name</i>	<i>NPI# (optional)</i>	<i>Surgeon or Physician</i>	<i>Primary, Additional, or Other</i>	<i>Main Program</i>	<i>Living Donor Component</i>	<i>Pediatric Component</i>
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Do any of the individuals listed above have OPTN transgressions? ☐ Yes ☐ No
If yes, provide the name of the individual(s) and the program's plan to ensure compliance:

Part 3: Program Coverage Plan

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

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

Instructions:

Complete the questions below and provide documentation where applicable.

Transplant Surgeon and Physician Coverage

Surgeons

Yes No

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

Yes No

☐ ☐ Do you have additional surgeons listed with the program? **If the answer is no, the program must request an exemption from the MPSC to operate as a transplant program sharing primary personnel with another transplant hospital, without additional transplant staff.**

☐ ☐ Is the **primary** transplant surgeon **onsite** full-time at this transplant hospital?
If the answer is no, please describe in detail the onsite arrangements:

☐ ☐ Does the **primary** transplant surgeon have **on-call responsibilities** at more than one transplant hospital at the same time? **If the answer is yes, please explain below:**

Physicians

Yes No

☐ ☐ Is this a single physician program?
If yes, provide a copy of the patient notice or protocol for providing patient notification.

☐ ☐ Does the transplant program have transplant physicians available 365 days a year, 24 hours a day, 7 days a week to provide program coverage?
If the answer is no, provide a written explanation that justifies the current level of coverage.

☐ ☐ Will any of the transplant physicians be on call simultaneously for two transplant programs more than 30 miles apart?
If the answer is yes, the program must request an exemption from the MPSC to operate as a transplant program sharing primary personnel with another transplant hospital, without additional transplant staff.

☐ ☐ Is the primary transplant physician designated as the primary transplant physician at more than one transplant hospital?
If yes, answer the question below.

Yes No

☐ ☐ Do you have additional physicians listed with the program?
If the answer is no, the program must request an exemption from the MPSC to operate as a transplant program sharing primary personnel with another transplant hospital, without additional transplant staff.

☐ ☐ Is the **primary** transplant physician **onsite** full-time at this transplant hospital?

If the answer is no, please describe in detail the onsite arrangements:

- ☐ ☐ Does the **primary** transplant physician have **on-call responsibilities** at more than one transplant hospital at the same time?

If the answer is yes, please explain below:

Patient Notification

Check the box below to attest to the following:

- ☐ The transplant program provides patients with a written summary of the Program Coverage Plan when placed on the waiting list and when there are any substantial changes in the program or its personnel.

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

Part 4: Program Director(s)

A 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	Credentials

Part 5: Primary Kidney Transplant Surgeon Requirements

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

Name

NPI # (optional)

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

- ☐ The surgeon has an M.D., D.O., or equivalent degree from another country with a current license to practice medicine in the hospital's state or jurisdiction.

Provide a copy of the surgeon's medical license and resume/CV/documentation of education to show proof of this requirement.

- ☐ The surgeon has been accepted onto the hospital's medical staff and is practicing on site at this hospital.

Provide documentation from the hospital credentialing committee that it has verified the surgeon's state license, board certification, training, and transplant continuing medical education, and that the surgeon is currently a member in good standing of the hospital's medical staff.

3. Certification. Check one and provide corresponding documentation:

- ☐ The surgeon is currently certified by the American Board of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, or the Royal College of Physicians and Surgeons of Canada.

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

- ☐ The surgeon has just completed training and is **pending certification** by the American Board of Urology. Therefore, the program is requesting conditional approval for 16 months to allow the surgeon time to complete urology board certification, with the possibility of renewal for one additional 16-month period.

Provide documentation supporting that training has been completed and urology board certification is pending, which must include the anticipated date of board certification and where the surgeon is in the process to be certified.

- ☐ The surgeon is without certification by the American Board of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, or the Royal College of Physicians and Surgeons of Canada or pending certification by the American Board of Urology.

If this option is selected:

- *The surgeon must be ineligible for American board certification. Provide an explanation why the individual is ineligible:*

- *Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that:*
 - o *the surgeon obtains 60 hours of Category I continuing medical education (CME) credits.*
 - o *the surgeon performs a self-assessment that is relevant to the individual's practice every three years, with a score of 75% or higher. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program.*
 - o *the transplant hospital document completion of this continuing education.*
- *Provide at least 2 two letters of recommendation from directors of designated transplant programs not employed by the applying hospital that address:*
 - o *why an exception is reasonable.*
 - o *the surgeon's overall qualifications to act as a primary kidney 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.*

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

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

5. Which of the following pathways is the proposed primary surgeon applying (check one, and complete the corresponding pathway section below):

- ☐ The **fellowship pathway**, as described in Section 55A. Formal 2-year Transplant Fellowship Pathway below.
- ☐ The **clinical experience pathway**, as described in Section 55B. Clinical Experience Pathway 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:

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

- ☐ *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. ***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 OPTN membership requirements.

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:

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.***

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

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

- ☐ *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:
 - the surgeon's overall qualifications to act as primary transplant surgeon.
 - the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
 - 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

1. Name of Proposed Primary Kidney Transplant Physician (as indicated in Part 2: Certificate of Assessment):

Name

NPI # (optional)

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

- ☐ The physician has an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.

Provide a copy of the physician's medical license and resume/CV/documentation of education to show proof of this requirement.

- ☐ The physician has been accepted onto the hospital's medical staff, and is practicing on site at this hospital.

Provide documentation from the hospital credentialing committee that it has verified the physician's state license, board certification, training, and transplant continuing medical education, and that the physician is currently a member in good standing of the hospital's medical staff.

3. Certification. Check one and provide corresponding documentation:

- ☐ The physician is currently certified in 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.

- ☐ The physician is without certification in nephrology by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada.

Note: Some pathways require certain boards and therefore this option may not be used.

- **The physician must be ineligible for American board certification. Provide an explanation why the individual is ineligible:**

- **Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that:**
 - o the physician obtains 60 hours of Category I continuing medical education (CME) credits.
 - o the physician performs a self-assessment that is relevant to the individual's practice every three years, with a score of 75% or higher. Self-assessment is

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

- o the transplant hospital document completion of this continuing education.*
- *Provide at least 2 two letters of recommendation from directors of designated transplant programs not employed by the applying hospital that address:*
 - o why an exception is reasonable.*
 - o The 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 Experience	Date (MM/DD/YY)		Transplant Hospital	Program Director
	Start	End		
Fellowship				
Experience Post Fellowship				

5. Which of the following pathways is the proposed primary physician applying? (check one, and complete the corresponding pathway section below):

- ☐ The **transplant nephrology fellowship pathway**, as described in *Section 55A. Transplant Nephrology Fellowship Pathway* 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 *Section 5Error: Reference source not found* below.
- ☐ The **combined pediatric nephrology training and experience pathway**, as described in *Section 5Error: Reference source not found* below.
- ☐ 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:

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 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.*
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:
 - the physician's overall qualifications to act as primary transplant physician.
 - the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
 - 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.
9. ***Check to attest to the following***

- ☐ *This physician's training was completed at a hospital with a recognized fellowship training program accepted by the OPTN Contractor as described in OPTN membership requirements.*

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

5B. Clinical Experience Pathway

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

1. *The physician has been directly involved in the primary care of **45 or more** newly transplanted kidney recipients and continued the outpatient follow-up of these recipients for 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:
 - the physician's overall qualifications to act as primary transplant physician.
 - the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
 - 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:

Check to attest to the following

☐ *This physician's training meets the requirements described 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 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.*
- ☐ *The physician has experience with immediate post-operative care including those issues of management unique to the pediatric recipient.*
- ☐ *The physician has experience with fluid and electrolyte management.*

- ☐ *The physician has experience with the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development.*
 - ☐ *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.*
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:***
- 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:
 - the physician's overall qualifications to act as primary transplant physician.
 - the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
 - any other matters judged appropriate.
- The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
- A letter from the physician that details the training and experience the physician has gained in kidney transplantation.

5D. Twelve-month Pediatric Transplant Nephrology Fellowship Pathway

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

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

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

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

This experience must be documented on 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.*

- ☐ *The physician has experience with immediate post-operative care including those issues of management unique to the pediatric recipient.*
 - ☐ *The physician has experience with fluid and electrolyte management.*
 - ☐ *The physician has experience with the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development.*
 - ☐ *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:
 - the physician's overall qualifications to act as primary transplant physician.
 - the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
 - any other matters judged appropriate.
- The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.

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

5E. Combined Pediatric Nephrology Training and Experience Pathway

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

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

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

2. 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.*

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.*

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.*

- ☐ *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 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 physician's overall qualifications to act as primary transplant physician.
 - the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
 - any other matters judged appropriate.
- The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
- A letter from the physician that details the training and experience the physician has gained in kidney transplantation.

5F. Conditional Approval for Primary Transplant Physician

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

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

This experience must be documented on 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.*
- ☐ *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:
 - the physician's overall qualifications to act as primary transplant physician.
 - the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations 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 OPTN requirements for both primary kidney surgeon and primary pediatric kidney surgeon, check the box in number 2 to identify the desired pathway and complete Part 5 of this application.

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

- Indicate the pathway in Number 2. To demonstrate that the proposed physician meets the OPTN requirements for both primary kidney physician and primary pediatric kidney physician, complete Part 6 of this 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 OPTN requirements.
 - 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

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

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

- ☐ The **fellowship pathway**, as described in Section 55A. *Formal 2-year Transplant Fellowship Pathway in Part 5: Primary Kidney Transplant Surgeon Requirements* above.
- ☐ The **clinical experience pathway**, as described in Section 55B. *Clinical Experience Pathway in Part 5: Primary Kidney Transplant Surgeon Requirements* above.

3. Pediatric-Specific Requirements

- 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 that can be verified by the OPTN.

- b. The surgeon has maintained a current working knowledge of pediatric kidney transplantation, defined as direct involvement in pediatric kidney transplant patient care within the last 2 years.

Check to attest to the following

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

Part 7B: Primary Pediatric Kidney Transplant Physician Requirements

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 Part 6 of this application):

- ☐ The **3-year pediatric nephrology fellowship pathway**, as described in *Section Error: 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.

- ☐ **Option A.** The program has a qualified primary pediatric kidney **physician** who meets *all* of the requirements described in **Part 7B: Primary Pediatric Kidney Transplant Physician Requirements** above and a **surgeon** who meets *all* of the following requirements:

1. **Name of proposed primary pediatric kidney transplant surgeon who meets conditional OPTN requirements:**

Name	NPI # (optional)
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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:
- ☐ 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.
 - ☐ 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 Part 5 of this application.
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 in the last 2 years.
Check to attest to the following
- ☐ The surgeon has experience with the management of pediatric patients with end stage renal disease.
 - ☐ The surgeon has experience with the selection of appropriate pediatric recipients for transplantation.
 - ☐ 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.
 - ☐ 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.
- ☐ **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 OPTN requirements:**

Name	NPI # (optional)
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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.
- ☐ The physician has experience managing the selection of appropriate pediatric recipients for

transplantation.

- ☐ 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.
- ☐ 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.
- ☐ The physician has experience with the 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 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.

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

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* 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.

Note: Some pediatric living donor or kidney paired donation transplants may require that the living organ 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 Policy.

Name of Independent Living Donor Advocate (ILDA): _____

Part 8A: 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)
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A kidney donor surgeon who performs open living donor nephrectomies must be on site. An open living donor nephrectomies surgeon must meet one of the following criteria:

Check one and provide corresponding documentation

- ☐ Completion of a **formal 2-year surgical transplant fellowship in kidney** at a fellowship program approved by the American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or other recognized fellowship training program accepted by the OPTN Contractor as described in OPTN membership requirements.
Provide this surgeon's certificate of completion of an approved fellowship in kidney.
- ☐ Completion of **at least 10** open nephrectomies, including deceased donor nephrectomies or the removal of diseased kidneys, as primary surgeon, co-surgeon, or first assistant. **At least 5** of these open nephrectomies must have been performed as the primary surgeon or co-surgeon.
This experience must be documented on 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.

Part 8B: Primary Laparoscopic Living Donor Kidney Surgeon

Name of Proposed Primary Laparoscopic Living Donor Kidney Surgeon (as indicated in Part 2: Certificate of Assessment):

Name	NPI # (optional)
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A surgeon who performs laparoscopic living donor kidney recoveries must be on site and must meet the following criteria:

- ☐ 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 experience.

6. Kidney Paired Donation (KPD)

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

The private, non-profit Organ Procurement and Transplantation Network (OPTN) collects this information in order to perform the following OPTN functions: to assess whether applicants meet OPTN membership requirements; and to monitor compliance of member organizations with OPTN Obligations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0915-0184 and it is valid until 12/31/2025. 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 Information Collection Clearance Officer, 5600 Fishers Lane, Room 14N39, Rockville, Maryland, 20857 or paperwork@hrsa.gov.