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

OPTN Membership Application for Pancreas 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.

	OPTI	N Representative	
Printed Name		Signature	Email Address
	Position _		
Printed Name	Email Address	Signature	
	Position _		
Printed Name	Email Address	Signature	
	Position _		

ſ	Printed Name	Email Address Position	Signature	
	Printed Name	Email Address	Signature	
		Position		
	Printed Name	Email Address	Signature	

Dart	1.	Gene	aral	Infor	mation
Part	T:	Gene	erai	Intor	mation

Name of Trans	plant Hosp	oital:			

OPTN Member Code (4 Letters):					
Transplant Hospital Address (where	e transplants o	ccur)			
Street:		Ste	9:	Phone #:	
City:	ST:	_ Zip:		Fax #:	
Name of Person Completing Form:				Title:	
Email Address of Person Completing	g Form:				
Date Form is submitted to OPTN Co	ontractor:				

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

Part 2: Program Director(s)

A pancreas transplant program must identify at least one designated s transplant program director. The director must be a physician or surge transplant hospital staff.		
Name of Program Director(s) (list all):	New	Existing

Include the resume/CV of each new individual listed.

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

Part 3: Primary Program Administrator

	A primary program administrator is the identified administrative lead for the transplant program.
ı	Complete this section only if you are updating the Primary Program Administrator position for the program.
	Name of Primary Program Administrator:
	Credentials:
	Title at Hospital:
	Phone Number:
	Email:

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

Part 4: Primary Data Coordinator

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

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

Part 5: Primary Pancreas Transplant Surgeon Requirements

1.	 Name of Proposed Primary Pancreas Transplant Surge Assessment): 	on (as indicated in Certificate of
	Name	NPI #
2.	. Check yes or no for each of the following. Provide doc	umentation where applicable:
	 2a. Does the surgeon have an M.D., D.O., or equivalent of current license to practice medicine in the hospital's statement of the surgeon's resume/CV. 2b. Has the surgeon been accepted onto the hospital's methics hospital? Provide documentation from the hospital credentialing surgeon's state license, board certification, training, and 	nte or jurisdiction? nedical staff, and is practicing on site at committee that it has verified the d transplant continuing medical
3.	education, and that the surgeon is currently a member medical staff. Certification. Check one and provide corresponding do	
	3a. The surgeon is currently certified by the American Urology, the American Board of Osteopathic Surgery of Physicians and Surgeons of Canada.	
	Provide a copy of the surgeon's current board certification. 3b. The surgeon has just completed training and is per Board of Urology. Therefore, the surgeon is requesting allow time to complete board certification, with the per 16-month period.	nding certification by the American g conditional approval for 16 months to
	Provide documentation supporting that training has be pending, which must include the anticipated date of be is in the process to be certified. 3c. The surgeon is without American Board of Surge American Board of Osteopathic Surgery, or the the R of Canada.	oard certification and where the surgeon ery, the American Board of Urology, the loyal College of Physicians and Surgeons
	 The surgeon must be ineligible for American boo why the individual is ineligible: 	ira certification. Provide an explanation

- Provide a plan for continuing education that is comparable to American board maintenance of certification; and
- Provide at least 2 two letters of recommendation from directors of designated transplant programs not employed by the applying hospital that address
 - **o** why an exception is reasonable,
 - the individual's overall qualifications to act as a primary pancreas transplant surgeon,
 - **o** the individual's personal integrity and honesty,
 - the individual's familiarity with and experience in adhering to OPTN obligations and compliance protocols, and
 - o any other matters judged appropriate.
- 4. Summarize the surgeon's training and experience in transplant:

Training	Approved Fellowshi p Program? Y/N					# of Pancreas	# of Pancreas	# of Pancreas Procurement
and Experience		Star t	End	Transplan t Hospital	Program Director	Transplant s as Primary	Transplants as First Assistant	s as Primary or 1 st Assistant
Fellowship Training								
Experience Post Fellowship								

5.	h of the following pathways is the proposed primary surgeon applying (check one, and plete the corresponding pathway section below):
	The fellowship pathway, as described in <i>Section 5</i> Name of Program Director(s) (list all): New Existing below.
	The clinical experience pathway, as described in Section 55B. Clinical Experience Pathway below.
	The alternative pathway for predominantly pediatric programs, as described in Section 55C. Alternate Pathway for Predominantly Pediatric Programs below.

dysfunction.

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

5A	, , ,
	rgeons can meet the training requirements for primary pancreas transplant surgeon by mpleting a formal 2-year surgical transplant fellowship if the following conditions are met:
1.	The surgeon has performed at least 15 pancreas transplants as primary surgeon or first assistant.
	This experience must be documented that includes date of transplant, role of the surgeon medical record number or other unique identifier, and the training program director's signature. log on a
2.	The surgeon has performed at least 10 pancreas procurements as primary surgeon or first assistant. These procurements must have been performed anytime during the surgeon's fellowship and the two years immediately following fellowship completion.
	This experience must be documented on a log that includes the date of procurement, Donor ID, and the training program director's signature.
3.	The surgeon has maintained a current working knowledge of pancreas transplantation,
	defined as direct involvement in patient care <u>within the last 2 years</u> . Check all that apply
	☐ The surgeon has experience managing patients with diabetes mellitus.
	☐ 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.
	 The surgeon has experience with immediate postoperative and continuing inpatient care.
	\Box The surgeon has experience with the use of immunosuppressive therapy including
	side effects of the drugs and complications of immunosuppression.
	$\hfill \square$ The surgeon has experience with differential diagnosis of pancreas dysfunction in
	the allograft recipient.
	$\ \square$ The surgeon has experience with histological interpretation of allograft biopsies.
	\Box The surgeon has experience with interpretation of ancillary tests for pancreatic

 $\hfill\Box$ The surgeon has experience with long term outpatient care.

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

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

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

The MPSC may request similar letters of recommendation 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 individual that details the training and experience they have gained in pancreas transplantation.

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

	- CI - I	-	B 41
5B.	Clinical	Experience	Pathway
JD.	Cillical	LAPCITCITC	I atiivvay

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

1. The surgeon has performed 20 or more pancreas transplants over a 2 to 5-year period as primary surgeon, co-surgeon, or first assistant, at a designated pancreas transplant program. Of these 20 pancreas transplants, 10 or more must have been performed as primary surgeon or co-surgeon. Each year of the surgeon's experience must be substantive and relevant and include pre-operative assessment of pancreas transplant candidates, transplants performed as primary surgeon or first assistant, and post-operative care of pancreas recipients.

This experience must be documented. that includes the date of transplant, the role of the surgeon, and medical record number or other unique identifierlog on a

- 2. The surgeon has performed at least 10 pancreas procurements as primary surgeon, cosurgeon, or first assistant. Of these 10 pancreas procurements, at least 5 must have been performed as primary surgeon or co-surgeon.
 - This experience must be documented .that includes the date of procurement, role of the surgeon, and Donor IDlog on a
- The surgeon has maintained a current working knowledge of pancreas transplantation, defined as direct involvement in patient care within the last 2 years.
 Check all that apply
 The surgeon has experience managing patients with diabetes mellitus.

☐ The surgeon has experience managing patients with diabetes mellitus.
\square 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.
\Box The surgeon has experience with performing the transplant operation.
☐ The surgeon has experience with immediate postoperative and continuing
inpatient care.
$\hfill \square$ The surgeon has experience with the use of immunosuppressive therapy including
side effects of the drugs and complications of immunosuppression.
$\hfill\Box$ The surgeon has experience with differential diagnosis of pancreas dysfunction in
the allograft recipient.
\Box The surgeon has experience with histological interpretation of allograft biopsies.
$\ \square$ The surgeon has experience with interpretation of ancillary tests for pancreatic
dysfunction.
☐ The surgeon has experience with long term outpatient care.

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

- 4. Provide the following letters with the application:
- A letter from the director of the transplant program and chairman of the department or hospital credentialing committee verifying that the fellow has met the above requirements and is qualified to direct a pancreas transplant program.
- A letter of recommendation from the training program's primary surgeon and transplant program director outlining
 - o the individual's overall qualifications to act as primary transplant surgeon,
 - 0 the individual's personal integrity and honesty,
 - o the individual's familiarity with and experience in adhering to OPTN obligations, and
 - o any other matters judged appropriate.

The MPSC may request similar letters of recommendation 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 individual that details the training and experience they have gained in pancreas transplantation.

5 C	Alternate Pathway for Predominantly Pediatric Programs
eit ab Mi	a surgeon does not meet the requirements for primary pancreas transplant surgeon through ther the 2-year transplant fellowship pathway or clinical experience pathway as described ove, transplant programs that serve predominantly pediatric patients may petition the PSC in writing to consider the surgeon for primary transplant surgeon if the program can monstrate that the following conditions are met:
1.	Provide an explanation why the proposed surgeon needs to utilize this pathway:
2.	The surgeon's pancreas transplant training or experience must be equivalent to the forma 2-year transplant fellowship pathway, as described in <i>Section 5</i> Name of Program Director(s) (list all): New Existing or the pancreas transplant program clinical
	experience pathway, as described in Section 55B. Clinical Experience Pathway This experience must be documented .that includes the date of transplant and/or
	This experience must be documented that includes the date of transplant and/or

	procurement, role of the surgeon, and Donor IDlog on a
3.	The surgeon has maintained a current working knowledge of all aspects of pancreas transplantation and patient care, defined as direct involvement in pancreas transplant patient care within the last 2 years. Check all that apply The surgeon has experience managing patients with diabetes mellitus. 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.
	\Box The surgeon has experience with performing the transplant operation.
	$\ \square$ 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.
	\Box The surgeon has experience with differential diagnosis of pancreas 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 pancreatic dysfunction.

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

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

- 4. The surgeon submits *letter(s)* of recommendation from the training program's primary surgeon and director at the fellowship training program or transplant program last served by the surgeon outlining
 - the individual's overall qualifications to act as a primary transplant surgeon,
 - the individual's personal integrity and honesty,
 - the individual's familiarity with and experience in adhering to OPTN obligations, and
 - any other matters judged appropriate.

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

5. If this pathway is selected, the OPTN contractor will contact the program to schedule an informal discussion with the MPSC.

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

Part 6: Primary Pancreas Transplant Physician Requirements

	ame of Proposed Primary Pancreas Transplant Physician ssessment):	(as indicated in Certificate of
	Name	NPI #
2. C	heck yes or no for each of the following. Provide docume	ntation where applicable:
Yes N	0	
	2a. Does the physician have an M.D., D.O., or equivalent current license to practice medicine in the hospital's sta physician's resume/CV.	
	2b. Has the physician been accepted onto the hospital's this hospital? Provide documentation from the hospital verified the physician's state license, board certification medical education, and that the physician is currently a hospital's medical staff.	credentialing committee that it has , training, and transplant continuing
3. C	ertification. Check one and provide corresponding docum	entation:
	3a. The physician is currently certified in in nephrology American Board of Internal Medicine, the American Bo of Physicians and Surgeons of Canada. Provide a copy certification.	oard of Pediatrics, or the Royal College
	3b. The physician is without certification in nephrolog American Board of Internal Medicine, the American E of Physicians and Surgeons of Canada. The physician must be ineligible for American board of the individual is ineligible:	Board of Pediatrics, or the Royal College
	 Provide a plan for continuing education that maintenance of certification; and Provide at least 2 two letters of recommendation programs not employed by the applying hospital the owney of the individual's overall qualifications to physician, the individual's personal integrity and homo the individual's familiarity with and expendent of the individual of the individua	from directors of designated transplant hat address act as a primary pancreas transplant esty,

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

o any other matters judged appropriate.

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

Training and	Approved Fellowshi	(MM	ate /DD/ Y)			#	PA Pati	ents Followed
Experience	p Program? Y/N	Star t	End	Transplan t Hospital	Program Director	Pre	Peri	Post
Fellowship Training								
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 12-month pancreas transplant fellowship pathway, as described in <i>Section 5</i> below.
	☐ The clinical experience pathway, as described in <i>Section 55B</i> . Clinical Experience Pathway below.
	☐ The alternative pathway for predominantly pediatric programs, as described in Section 55C. Alternative Pathway for Predominantly Pediatric Programs below.
	\Box The conditional approval pathway, as described in Section 55D. Conditional Approval for
	Primary Transplant Physician below, if the primary pancreas transplant physician changes at an approved pancreas transplant program.

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

	5A.	Twelve-month	Transplant Medic	ine Fellowship Pathway	٧
--	-----	--------------	------------------	------------------------	---

Physicians can meet the training requirements for a primary pancreas transplant physician during a separate 12-month transplant medicine fellowship if the following conditions are met:

- 1. The physician completed 12 consecutive months of specialized training in pancreas transplantation at a pancreas transplant program under the direct supervision of a qualified pancreas transplant physician along with a pancreas transplant surgeon. The training must have included at least 6 months on the clinical 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 8 or more newly transplanted pancreas recipients and followed these recipients for a minimum of 3 months from the time of transplant.
 This experience must be documented that includes the date of transplant, medical record number or other unique identifier, and the signature of the director of the training program or the primary transplant physician. log on a

3.	The physician has maintained a current working knowledge of pancreas transplantation,
	defined as direct involvement in pancreas transplant patient care within the last 2 years.
	Check all that apply
	$\ \square$ The physician has experience managing patients with end stage pancreas disease.
	\square The physician has experience with the selection of appropriate recipients for
	transplantation.
	\square The physician has experience with donor selection.
	\square The physician has experience with histocompatibility and tissue typing.
	\square The physician has experience with immediate post-operative patient care.
	\square The physician has experience with the use of immunosuppressive therapy including
	side effects of the drugs and complications of immunosuppression.
	\square The physician has experience with differential diagnosis of pancreas dysfunction in
	the allograft recipient.
	\Box The physician has experience with histological interpretation of allograft biopsies.
	\square The physician has experience with interpretation of ancillary tests for pancreas
	dysfunction.
	\Box The physician has experience with long term outpatient care.

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

- 4. The physician has observed at least 3 pancreas procurements. The physician must have also observed the evaluation, donation process, and management of these donors.

 This experience must be documented on .that includes the date of procurement and Donor ID log a
- 5. The physician has observed at least 3 pancreas transplants.

 This experience must be documented on .that includes the transplant date and medical record number or other unique identifier log a
- 6. Provide the following letters with the application:
 - A letter from director of the training program and supervising qualified pancreas transplant physician send a letter directly to the OPTN Contractor verifying that the fellow has met the above requirements and is qualified to direct a pancreas transplant program.
 - A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining
 - o the individual's overall qualifications to act as primary transplant physician,
 - 0 the individual's personal integrity and honesty, and
 - o the individual's familiarity with and experience in adhering to OPTN obligations, and
 - o any other matters judged appropriate.

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

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

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

5B.	Clinical	Experience	Dathway
JD.	CIIIIICai	EXDELICITE	rallivvav

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

1. The physician has been directly involved in the primary care of 15 or more newly transplanted pancreas recipients and continued to follow 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 pancreas transplant service as the primary pancreas transplant physician or under the direct supervision of a qualified pancreas transplant physician along with a pancreas transplant surgeon at a designated pancreas transplant program.

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

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

3. The physician has observed at least 3 pancreas procurements. The physician must have observed the evaluation, donation process, and management of these donors.

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

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

- 4. The physician has observed at least 3 pancreas transplants.

 This experience must be documented .that includes the transplant date and medical record number or other unique identifier log on a
- 5. Provide the following letters with the application:
 - A letter from director of the training program and supervising qualified pancreas transplant physician send a letter directly to the OPTN Contractor verifying that the fellow has met the above requirements and is qualified to direct a pancreas transplant program.
 - A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining
 - o the individual's overall qualifications to act as primary transplant physician,
 - 0 the individual's personal integrity and honesty,
 - o the individual's familiarity with and experience in adhering to OPTN obligations, and
 - o any other matters judged appropriate.

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

• A letter from the individual that details the training and experience they have gained in pancreas transplantation.

5C.	Alternative Pathway for Predominantly Pediatric Programs
fell pre for	physician does not meet the requirements for primary physician through the transplant lowship or clinical experience pathways as described above, transplant programs that serve edominantly pediatric patients may petition the MPSC in writing to consider the physician primary transplant physician if the program can demonstrate that the following conditions emet:
1.	Provide an explanation why the proposed physician needs to utilize this pathway:
2.	That the physician's pancreas transplant training or experience is equivalent to the
	fellowship or clinical experience pathways as described in the 12-month pancreas transplant fellowship pathway, as described in <i>Section 5</i> below or the clinical experience pathway, as described in <i>Section 55B</i> . Clinical Experience Pathway above. This experience must be documented that includes the date of transplant and/or
	procurement,log on a and Donor ID.
3.	The physician has maintained a current working knowledge of all aspects of pancreas
	transplantation, defined as direct involvement in pancreas transplant patient care <u>within</u>
	the last 2 years.
	Check all that apply ☐ The physician has experience managing patients with end stage pancreas disease.
	☐ The physician has experience with the selection of appropriate recipients for transplantation.
	☐ The physician has experience with donor selection.
	$\ \square$ The physician has experience with histocompatibility and tissue typing.
	\square The physician has experience with immediate post-operative patient care.
	\square 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 pancreas 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 pancreas
	dysfunction.

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

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

- 4. Provide letter(s) of recommendation from the primary physician and transplant program director at the fellowship program or transplant program last served by the physician outlining
 - the individual's overall qualifications to act as a primary transplant physician,
 - the individual's personal integrity and honesty,
 - the individual's familiarity with and experience in adhering to OPTN obligations, and
 - any other matters judged appropriate.

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

5. If this pathway is selected, the OPTN contractor will contact the program to schedule an informal discussion with the MPSC.

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

5D.	Conditional Approval for Primary Transplant Physician
prog	e primary pancreas transplant physician changes at an approved pancreas transplant gram, a physician can serve as the primary pancreas transplant physician for a maximum of
12 n	nonths if the following conditions are met:
	The physician has been involved in the primary care of 8 or more newly transplanted pancreas recipients, and has followed these patients for at least 3 months from the time of their transplant.
	This experience must be documented .includes the date of transplant and medical record number or other unique identifier that log on a
	The physician has maintained a current working knowledge of pancreas transplantation, defined as direct involvement in pancreas transplant patient care within the last 2 years. Check all that apply
	 The physician has experience managing patients with end stage pancreas disease. The physician has have 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 post-operative patient care. The physician has experience with the use of immunosuppressive therapy including
	☐ 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 pancreas 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 pancreas dysfunction.
	$\ \square$ The physician has experience with long term outpatient care.
	If a box is not checked, please provide an explanation:
2	The physician has 12 months experience on an active nancycas transplant service as the
	The physician has 12 months experience on an active pancreas transplant service as the primary pancreas transplant physician or under the direct supervision of a qualified pancreas transplant physician along with a pancreas transplant surgeon at a designated pancreas transplant program. This 12 month paried of experience on the transplant
	pancreas transplant program. This 12-month period of experience on the transplant service must have been acquired over a maximum of 2 years.
4.	The physician has observed at least 3 pancreas procurements. The physician must have

observed the evaluation, donation process, and management of these donors.

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

This experience must be documented . that includes the date of procurement and Donor ID logon a

- 5. The physician has observed at least 3 pancreas transplants.

 This experience must be documented .that includes the transplant date and medical record number or unique identifier log on a
- 6. Provide documentation that supports that the program has established and documented a consulting relationship with counterparts at another pancreas transplant program.
- 7. Provide documentation that the transplant program will submit activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress in meeting the required involvement in the primary care of 15 or more pancreas transplant recipients, or that the program is making sufficient progress in recruiting a physician 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.
- **8.** Provide the following letters with the application:
 - A letter from the qualified pancreas transplant physician and surgeon who were directly involved with the physician documenting the physician's experience and competence.
 - A letter of recommendation from the primary physician and director at the transplant program last served by the physician outlining
 - o the individual's overall qualifications to act as a primary transplant physician,
 - o the individual's personal integrity and honesty
 - The individual's familiarity with and experience in adhering to OPTN obligations, and
 - o any other matters judged appropriate.
 - The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
 - A letter from the physician that details the training and experience the physician has gained in pancreas transplantation.

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

Part 7: Pediatric Transplant Component

Pancreas Transplant Programs that Register Candidates Less than 18 Years Old

A designated pancreas 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 pancreas transplant program must identify a qualified primary pediatric pancreas transplant surgeon and a qualified primary pediatric pancreas transplant physician, as described below.

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

Part 7A: Primary Pediatric Pancreas Transplant Surgeon Requirements

	Name	NPI#
2	2. Check yes or no for each of the following. Provide of	documentation where applicable:
Yes I	No	
	\square 2a. Does the surgeon have an M.D., D.O., or equivale	
	current license to practice medicine in the hospital's	state or jurisdiction?
	Provide a copy of the surgeon's resume/CV.	
	2b. Has the surgeon been accepted onto the hospital this hospital?	s medical staff, and is practicing on site at
	Provide documentation from the hospital credential	ing 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 memb	per in good standing of the hospital's
	medical staff.	
;	3. Certification. Check one and provide corresponding	documentation:
	3a. The surgeon is currently certified by the Americ	an Board of Surgery, the American Board of
	Urology, the American Board of Osteopathic Surge	ry or currently certified by the Royal College
	of Physicians and Surgeons of Canada. Provide a copy of the surgeon's current board certi	fication
П	3b. The surgeon has just completed training and is	
	Board of Urology. Therefore, the surgeon is request	
	allow time to complete board certification, with the	
	16-month period.	
	20 111011111 por 10011	
	Provide documentation supporting that training ha	s been completed and certification is
	•	
	Provide documentation supporting that training ha	
	Provide documentation supporting that training had pending, which must include the anticipated date of is in the process to be certified. 3c. The surgeon is without American Board of Su	of board certification and where the surgeon rgery, the American Board of Urology, the
	Provide documentation supporting that training had pending, which must include the anticipated date of is in the process to be certified. 3c. The surgeon is without American Board of Su American Board of Osteopathic Surgery, or the R	of board certification and where the surgeon rgery, the American Board of Urology, the
	Provide documentation supporting that training had pending, which must include the anticipated date of is in the process to be certified. 3c. The surgeon is without American Board of Su	of board certification and where the surgeon rgery, the American Board of Urology, the oyal College of Physicians and Surgeons of

- Provide a plan for continuing education that is comparable to American board maintenance of certification; and
- Provide at least 2 two letters of recommendation from directors of designated transplant programs not employed by the applying hospital that address
 - **o** why an exception is reasonable,
 - the individual's overall qualifications to act as a primary pancreas transplant surgeon,
 - the individual's personal integrity and honesty,
 - the individual's familiarity with and experience in adhering to OPTN obligations and compliance protocols, and
 - o any other matters judged appropriate.
- 4. Summarize the surgeon's training and experience in transplant:

	Training and Experience	Approved Fellowshi p Program? Y/N	Date (MM/DD/ YY)				# of PA Transplant	# of PA Transplants	# of PA Procurement s as Primary
			Star t	End	Transplan t Hospital	Program Director	s as Primary	as First Assistant	or 1 st Assistant
	Fellowship Training								
	Experience Post Fellowship								

5.	ch of the following pathways is the proposed primary surgeon applying (check one, and plete the corresponding pathway section below):
	The formal 2-year transplant fellowship pathway, as described in Section 5Name of
	Program Director(s) (list all): New Existing below.
	The pancreas transplant program clinical experience pathway, as described in <i>Section 55B. Clinical Experience Pathway</i> below.
	The alternative pathway for predominantly pediatric programs, as described in Section 55C. Alternate Pathway for Predominantly Pediatric Programs below.

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

5A	. Formal 2-year Transplant Fellowship Pathway
	rgeons can meet the training requirements for primary pancreas transplant surgeon by mpleting a formal 2-year surgical transplant fellowship if the following conditions are met:
1.	The surgeon has performed at least 15 pancreas transplants as primary surgeon or first assistant.
	This experience must be documented that includes the date of transplant, role of the surgeon, medical record number or other unique identifier, and the fellowship director's signature.log on a
2.	The surgeon has performed at least 10 pancreas procurements as primary surgeon or first assistant. These procurements must have been performed anytime during the surgeon's fellowship and the two years immediately following fellowship completion. This experience must be documented that includes the date of procurement, Donor ID, and the training program director's signature. log on a
3.	The surgeon has maintained a current working knowledge of pancreas transplantation, defined as direct involvement in patient care within the last 2 years. Check all that apply The surgeon has experience managing patients with diabetes mellitus. 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 pancreas 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 pancreatic

 \Box The surgeon has experience with long term outpatient care.

4. Provide the following letters with the application:

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

dysfunction.

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

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

The MPSC may request similar letters of recommendation 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 individual that details the training and experience they have gained in pancreas transplantation.

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

	61: I		B 41
5B.	(Tinical	Experience	Pathway
JD.	CIIIIICUI	LAPCITCITC	I atiivvay

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

1. The surgeon has performed 20 or more pancreas transplants over a 2 to 5-year period as primary surgeon, co-surgeon, or first assistant, at a designated pancreas transplant program. Of these 20 pancreas transplants, 10 or more must have been performed as primary surgeon or co-surgeon. Each year of the surgeon's experience must be substantive and relevant and include pre-operative assessment of pancreas transplant candidates, transplants performed as primary surgeon or first assistant, and post-operative care of pancreas recipients.

This experience must be documented. that includes the date of transplant, the role of the surgeon, and medical record number or other unique identifierlog on a

- 2. The surgeon has performed at least 10 pancreas procurements as primary surgeon, cosurgeon, or first assistant. Of these 10 pancreas procurements, at least 5 must have been performed as primary surgeon or co-surgeon.
 - This experience must be documented .that includes the date of procurement, role of the surgeon, and Donor IDlog on a
- 3. The surgeon has maintained a current working knowledge of pancreas transplantation, defined as direct involvement in patient care within the last 2 years.

 Check all that apply

ook an that appry
☐ The surgeon has experience managing patients with diabetes mellitus.
\Box 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.
\Box 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 pancreas dysfunction in
the allograft recipient.
\Box The surgeon has experience with histological interpretation of allograft biopsies.
☐ The surgeon has experience with interpretation of ancillary tests for pancreatic
dysfunction.
☐ The surgeon has experience with long term outpatient care.

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

- 4. Provide the following letters with the application:
- A letter from the director of the training program and chairman of the department or hospital credentialing committee verifying that the fellow has met the above requirements and is qualified to direct a pancreas transplant program.
- A letter of recommendation from the fellowship training program's primary surgeon and transplant program director outlining
 - o the individual's overall qualifications to act as primary transplant surgeon,
 - o the individual's personal integrity and honesty,
 - o the individual's familiarity with and experience in adhering to OPTN obligations, and
 - o any other matters judged appropriate.
 - The MPSC may request similar letters of recommendation 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 individual that details the training and experience they have gained in pancreas transplantation.

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

eitl abo MP	surgeon does not meet the requirements for primary pancreas transplant surgeon througher the 2-year transplant fellowship pathway or clinical experience pathway as described ove, transplant programs that serve predominantly pediatric patients may petition the PSC in writing to consider the surgeon for primary transplant surgeon if the program can monstrate that the following conditions are met:
1.	Provide an explanation why the proposed surgeon needs to utilize this pathway:
2.	The surgeon's pancreas transplant training or experience must be equivalent to the form 2-year transplant fellowship pathway, as described in Section 5Name of Program Director(s) (list all): New Existing or the pancreas transplant program clinical experience pathway, as described in Section 55B. Clinical Experience Pathway This experience must be documented. that includes the date of transplant and/or procurement, the role of the surgeon, and medical record number or other unique identifierlog on a
3.	The surgeon has maintained a current working knowledge of all aspects of pancreas transplantation and patient care, defined as direct involvement in pancreas transplant patient care within the last 2 years. Check all that apply The surgeon has experience managing patients with diabetes mellitus. The surgeon has experience with the selection of appropriate recipients for transplantation.
	☐ The surgeon has experience with donor selection.
	$\ \square$ The surgeon has experience with histocompatibility and tissue typing.
	$\ \square$ The surgeon has experience with performing the transplant operation.
	$\ \square$ The surgeon has experience with immediate postoperative and continuing
	inpatient care.
	☐ 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 pancreas dysfunction in the allograft recipient.

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

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

$\ \square$ The surgeon has experience with interpretation of ancillary tests for pancrea
dysfunction.
\square The surgeon has experience with long term outpatient care.
If a box is not checked, please provide an explanation:

- 4. The surgeon submits *letter(s)* of recommendation from the training program's primary surgeon and director at the fellowship training program or transplant program last served by the surgeon outlining
 - the individual's overall qualifications to act as a primary transplant surgeon,
 - the individual's personal integrity and honesty,
 - the individual's familiarity with and experience in adhering to OPTN obligations, and
 - any other matters judged appropriate.

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

5. If this pathway is selected, the OPTN contractor will contact the program to schedule an informal discussion with the MPSC.

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

Part 7B: Primary Pediatric Pancreas Transplant Physician Requirements

1. Name of Proposed Primary Pediatric Pancreas Transpl Assessment):	ant Physician (as indicated in Certificate of
Name Name	NPI #
2. Check yes or no for each of the following. Provide doc	umentation where applicable:
Yes No	
2a. Does the physician have an M.D., D.O., or equive current license to practice medicine in the hospital' physician's resume/CV.	
☐ ☐ 2b. Has the physician been accepted onto the hospit this hospital?	tal's medical staff, and is practicing on site at
Provide documentation from the hospital credential physician's state license, board certification, training education, and that the physician is currently a medical staff.	ng, and transplant continuing medical
3. Certification. Check one and provide corresponding do	ocumentation:
3a. The physician is currently certified in in nephro American Board of Internal Medicine, the America of Physicians and Surgeons of Canada.	
Provide a copy of the physician's current board ce	rtification.
☐ 3b. The physician is without certification in nephroman American Board of Internal Medicine, the America of Physicians and Surgeons of Canada. The physician must be ineligible for American boothe individual is ineligible:	can Board of Pediatrics, or the Royal College
Provide a plan for continuing education	that is comparable to American board
 maintenance of certification; and Provide at least 2 two letters of recommenda programs not employed by the applying hospi why an exception is reasonable, 	· · · · · · · · · · · · · · · · · · ·
	s to act as a primary pancreas transplant

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

Training and	Approved Fellowshi p	Date (MM/DD/ YY)		Transpla		# PA Patients Followed		
Experience	Program? Y/N	Star t	End	nt Hospital	Program Director	Pre	Peri	Post
Fellowship Training								
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 12-month pancreas transplant fellowship pathway, as described in <i>Section 5</i> below.
	☐ The clinical experience pathway, as described in Section 55B. Clinical Experience Pathway
	below.
	☐ The alternative pathway for predominantly pediatric programs, as described in Section 55C.
	Alternative Pathway for Predominantly Pediatric Programs below.
	\Box The conditional approval pathway, as described in Section 55D. Conditional Approval for
	Primary Transplant Physician below, if the primary pancreas transplant physician changes at an approved pancreas transplant program.

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

		- 1		-			D (1)
-	. ^		-month	Iranchian	t Madicina	LAHOWichin	Dathway
J	A.	IVVEIVE	-11101141	i i ai isbiai	LIVICUICITIE	Fellowship	rauiwav

Physicians can meet the training requirements for a primary pancreas transplant physician during a separate 12-month transplant medicine fellowship if the following conditions are met:

- 1. The physician completed 12 consecutive months of specialized training in pancreas transplantation at a pancreas transplant program under the direct supervision of a qualified pancreas transplant physician along with a pancreas transplant surgeon. The training must have included at least 6 months on the clinical 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 8 or more newly transplanted pancreas recipients and followed these recipients for a minimum of 3 months from the time of transplant.
 This experience must be documented that includes the date of transplant, medical record number or other unique identifier, and the signature of the director of the training program or the primary transplant physician. log on a

3.	The physician has maintained a current working knowledge of pancreas transplantation,
	defined as direct involvement in pancreas transplant patient care within the last 2 years.
	Check all that apply
	$\ \square$ The physician has experience managing patients with end stage pancreas disease.
	$\ \square$ The physician has experience with the selection of appropriate recipients for
	transplantation.
	\square The physician has experience with donor selection.
	$\ \square$ The physician has experience with histocompatibility and tissue typing.
	\square The physician has experience with immediate post-operative patient care.
	\square The physician has experience with the use of immunosuppressive therapy including
	side effects of the drugs and complications of immunosuppression.
	$\ \square$ The physician has experience with differential diagnosis of pancreas dysfunction in
	the allograft recipient.
	$\ \square$ The physician has experience with histological interpretation of allograft biopsies.
	$\ \square$ The physician has experience with interpretation of ancillary tests for pancreas
	dysfunction.
	\square The physician has experience with long term outpatient care.

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

- 4. The physician has observed at least 3 pancreas procurements. The physician must have also observed the evaluation, donation process, and management of these donors. This experience must be documented on .that includes the date of procurement and Donor ID log a
- 5. The physician has observed at least 3 pancreas transplants.

 This experience must be documented on .that includes the transplant date and medical record number or other unique identifier log a
- 6. Provide the following letters with the application:
 - A letter from director of the training program and supervising qualified pancreas transplant physician send a letter directly to the OPTN Contractor verifying that the fellow has met the above requirements and is qualified to direct a pancreas transplant program.
 - A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining
 - o the individual's overall qualifications to act as primary transplant physician,
 - 0 the individual's personal integrity and honesty, and
 - o the individual's familiarity with and experience in adhering to OPTN obligations, and
 - o any other matters judged appropriate.

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

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

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

5B.	Clinical	Experience	Pathway

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

1. The physician has been directly involved in the primary care of 15 or more newly transplanted pancreas recipients and continued to follow 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 pancreas transplant service as the primary pancreas transplant physician or under the direct supervision of a qualified pancreas transplant physician along with a pancreas transplant surgeon at a designated pancreas transplant program.

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

2. The physician has maintained a current working knowledge of pancreas transplantation,

 □ 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 post-operative patient care. □ The physician has experience with the use of immunosuppressive therapy includin side effects of the drugs and complications of immunosuppression. □ The physician has experience with differential diagnosis of pancreas 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 pancreas dysfunction. □ The physician has experience with long term outpatient care. 		extstyle The physician has experience managing patients with end stage pancreas disease.
 □ The physician has experience with donor selection. □ The physician has experience with histocompatibility and tissue typing. □ The physician has experience with immediate post-operative patient care. □ The physician has experience with the use of immunosuppressive therapy includin side effects of the drugs and complications of immunosuppression. □ The physician has experience with differential diagnosis of pancreas 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 pancreas dysfunction. 		☐ The physician has experience with the selection of appropriate recipients for
 □ The physician has experience with histocompatibility and tissue typing. □ The physician has experience with immediate post-operative patient care. □ The physician has experience with the use of immunosuppressive therapy includin side effects of the drugs and complications of immunosuppression. □ The physician has experience with differential diagnosis of pancreas 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 pancreas dysfunction. 	tı	ransplantation.
 □ The physician has experience with immediate post-operative patient care. □ The physician has experience with the use of immunosuppressive therapy includin side effects of the drugs and complications of immunosuppression. □ The physician has experience with differential diagnosis of pancreas 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 pancreas dysfunction. 		☐ The physician has experience with donor selection.
 □ 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 pancreas 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 pancreas dysfunction. 		☐ The physician has experience with histocompatibility and tissue typing.
side effects of the drugs and complications of immunosuppression. The physician has experience with differential diagnosis of pancreas 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 pancreas dysfunction.		☐ The physician has experience with immediate post-operative patient care.
 □ The physician has experience with differential diagnosis of pancreas 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 pancreas dysfunction. 		The physician has experience with the use of immunosuppressive therapy including
the allograft recipient. ☐ The physician has experience with histological interpretation of allograft biopsies. ☐ The physician has experience with interpretation of ancillary tests for pancreas dysfunction.	SI	
☐ The physician has experience with histological interpretation of allograft biopsies. ☐ The physician has experience with interpretation of ancillary tests for pancreas dysfunction.		
\Box The physician has experience with interpretation of ancillary tests for pancreas dysfunction.		
dysfunction.		
\Box The physician has experience with long term outpatient care.	d	ysfunction.
		☐ The physician has experience with long term outpatient care.

3. The physician has observed at least 3 pancreas procurements. The physician must have observed the evaluation, donation process, and management of these donors.

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

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

- 4. The physician has observed at least 3 pancreas transplants.

 This experience must be documented .that includes the transplant date and medical record number or other unique identifier log on a
- 5. Provide the following letters with the application:
 - A letter from director of the training program and supervising qualified pancreas transplant physician send a letter directly to the OPTN Contractor verifying that the fellow has met the above requirements and is qualified to direct a pancreas transplant program.
 - A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining
 - o the individual's overall qualifications to act as primary transplant physician,
 - 0 the individual's personal integrity and honesty,
 - 0 the individual's familiarity with and experience in adhering to OPTN obligations, and
 - o any other matters judged appropriate.

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

• A letter from the individual that details the training and experience they have gained in pancreas transplantation.

5C.	Alternative Pathway for Predominantly Pediatric Programs
fell pre for	physician does not meet the requirements for primary physician through the transplant lowship or clinical experience pathways as described above, transplant programs that serve edominantly pediatric patients may petition the MPSC in writing to consider the physician primary transplant physician if the program can demonstrate that the following conditions e met:
1.	Provide an explanation why the proposed physician needs to utilize this pathway:
2.	The physician's pancreas transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in the 12-month pancreas transplant fellowship pathway, as described in Section 5 below or the clinical experience pathway, as described in Section 55B. Clinical Experience Pathway above. This experience must be documented .that includes the date of transplant and/or procurement and medical record number or other unique identifier log on a
3.	The physician has maintained a current working knowledge of all aspects of pancreas transplantation, defined as direct involvement in pancreas transplant patient care within the last 2 years. Check all that apply The physician has experience managing patients with end stage pancreas 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 post-operative 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 pancreas 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 pancreas dysfunction.
	☐ The physician has experience with long term outpatient care.

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

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

- 4. Provide letter(s) of recommendation from the primary physician and transplant program director at the fellowship program or transplant program last served by the physician outlining
 - the individual's overall qualifications to act as a primary transplant physician,
 - the individual's personal integrity and honesty,
 - the individual's familiarity with and experience in adhering to OPTN obligations, and
 - any other matters judged appropriate.

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

5. If this pathway is selected, the OPTN contractor will contact the program to schedule an informal discussion with the MPSC.

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

5D	. Conditional Approval for Primary Transplant Physician
pro	he primary pancreas transplant physician changes at an approved pancreas transplant ogram, a physician can serve as the primary pancreas transplant physician for a maximum of months if the following conditions are met:
1.	The physician has been involved in the primary care of 8 or more newly transplanted pancreas recipients, and has followed these patients for at least 3 months from the time of their transplant. This experience must be documented .includes the date of transplant and medical record number or other unique identifier that log on a
2.	The physician has maintained a current working knowledge of pancreas transplantation, defined as direct involvement in pancreas transplant patient care within the last 2 years. Check all that apply The physician has experience managing patients with end stage pancreas 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 post-operative 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 pancreas 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 pancreas dysfunction. The physician has experience with long term outpatient care.
	If a box is not checked, please provide an explanation:
3.	The physician has 12 months experience on an active pancreas transplant service as the primary pancreas transplant physician or under the direct supervision of a qualified pancreas transplant physician along with a pancreas transplant surgeon at a designated pancreas transplant program. This 12-month period of experience on the transplant service must have been acquired over a maximum of 2 years.
4.	The physician has observed at least 3 pancreas procurements. The physician must have

observed the evaluation, donation process, and management of these donors.

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

This experience must be documented . that includes the date of procurement and Donor ID logon a

- 5. The physician has observed at least 3 pancreas transplants.

 This experience must be documented .that includes the transplant date and medical record number or unique identifier log on a
- 6. Provide documentation that supports that the program has established and documented a consulting relationship with counterparts at another pancreas transplant program.
- 7. Provide documentation that the transplant program will submit activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress in meeting the required involvement in the primary care of 15 or more pancreas transplant recipients, or that the program is making sufficient progress in recruiting a physician 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.
- **8.** Provide the following letters with the application:
 - A letter from the qualified pancreas transplant physician and surgeon who were directly involved with the physician documenting the physician's experience and competence.
 - A letter of recommendation from the primary physician and director at the transplant program last served by the physician outlining
 - o the individual's overall qualifications to act as a primary transplant physician,
 - o the individual's personal integrity and honesty
 - The individual's familiarity with and experience in adhering to OPTN obligations, and
 - o any other matters judged appropriate.
 - The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
 - A letter from the physician that details the training and experience the physician has gained in pancreas transplantation.

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

PUBLIC BURDEN STATEMENT

The private, non-profit Organ Procurement and Transplantation Network (OPTN) collects this information in order to perform the following OPTN functions: to assess whether applicants meet OPTN Bylaw requirements for membership in the OPTN; and to monitor compliance of member organizations with OPTN Obligations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0915-0184 and it is valid until 08/31/2023. This information collection is required to obtain or retain a benefit per 42 CFR §121.11(b) (2). All data collected will be subject to Privacy Act protection (Privacy Act System of Records #09-15-0055). Data collected by the private non-profit OPTN also are well protected by a number of the Contractor's security features. The Contractor's security system meets or exceeds the requirements as prescribed by OMB Circular A-130, Appendix III, Security of Federal Automated Information Systems, and the Departments Automated Information Systems Security Program Handbook. The public reporting burden for this collection of information is estimated to average 3 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 14N136B, Rockville, Maryland, 20857 or paperwork@hrsa.gov.