

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.

OPTN Representative

Printed Name

Signature

Email Address

Part 1: General Information

Name of Transplant Hospital: _____

OPTN Member Code (4 Letters): _____

Transplant Hospital Address (where transplants occur)

Street: _____ Suite: _____

City: _____ State: _____ Zip: _____

Pancreas Transplant Program Phone #: _____

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.*

Name	NPI# (optional)	Surgeon or Physician	Primary, Additional, or Other	Main Program	Pediatric Component
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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 pancreas 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 Pancreas Transplant Surgeon Requirements

1. Name of applicant (as indicated in Part 2: Certificate of Assessment):

Name	NPI # (optional)

- ☐ The applicant is being proposed as the Primary Pancreas Transplant Surgeon
- ☐ The applicant is being proposed as the Primary Pediatric Pancreas Transplant Surgeon

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

- ☐ The surgeon has a 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 must be 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 currently certified by 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 surgeon is requesting conditional approval for 16 months to allow 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 pancreas transplant surgeon.
 - o The surgeon's personal integrity and 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 5Program Director(s) (list all): 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.

5A. Formal 2-year Transplant Fellowship Pathway

Surgeons can meet the training requirements for primary pancreas transplant surgeon by completing 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 during the 2-year fellowship period.

This experience must be documented on a log that includes date of transplant, role of the surgeon, medical record number or other unique identifier that can be verified by the OPTN, and the fellowship director's signature.

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 fellowship director's signature.

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 to attest to the following

- ☐ 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 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 pancreas transplant training program approved by the American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or another recognized 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 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 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.
 - 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 surgeon that details the training and experience they have gained in pancreas transplantation.

5B. Clinical Experience Pathway

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 on a log that includes the date of transplant, the role of the surgeon, and medical record number or other unique identifier that can be verified by the OPTN.

2. *The surgeon has performed **at least 10** pancreas procurements as primary surgeon, co-surgeon, 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 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 pancreas transplantation, defined as direct involvement in patient care within the last 2 years.*

Check to attest to the following

- ☐ *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 dysfunction.*
- ☐ *The surgeon has experience with long term outpatient care.*

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 surgeon has met the above requirements and is qualified to direct a pancreas transplant program.
- A letter of recommendation from the primary surgeon and director at the transplant program last served by the surgeon outlining:
 - o The surgeon's overall qualifications to act as primary transplant surgeon.
 - o The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations.
 - 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 surgeon that details the training and experience they have gained in pancreas transplantation.

5C. Alternate Pathway for Predominantly Pediatric Programs

If a surgeon does not meet the requirements for primary pancreas transplant surgeon through either the 2-year transplant fellowship pathway or clinical experience pathway as described above, transplant programs that serve predominantly pediatric patients may petition the MPSC in writing to consider the surgeon for primary transplant surgeon if the program can demonstrate 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 is equivalent to the **formal 2-year transplant fellowship pathway**, as described in Section 5Program Director(s) (list all): or the **pancreas transplant program clinical experience pathway**, as described in Section 55B. Clinical Experience Pathway**
Provide documentation that supports equivalent training and experience, such as a log that includes the date of transplant and/or procurement, role of the surgeon, and medical record number or other unique identifier that can be verified by the OPTN.

3. Check to attest to the following

- ☐ 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.

- 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 surgeon's overall qualifications to act as a primary transplant surgeon.
- The surgeon'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 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.**

Part 6: Primary Pancreas Transplant Physician Requirements

1. Name of applicant (as indicated in Part 2: Certificate of Assessment):

Name	NPI # (optional)
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- ☐ The applicant is being proposed as the Primary Pancreas Transplant Physician
- ☐ The applicant is being proposed as the Primary Pediatric Pancreas Transplant Physician

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

- ☐ The physician has a 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, endocrinology, or diabetology 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, endocrinology, or diabetology by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada.

If this option is selected:

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

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- **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 pancreas transplant physician.*
 - o *The physician's personal integrity and 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 **12-month pancreas transplant fellowship pathway**, as described in *Section 5* 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.
- ☐ The **conditional approval pathway**, as described in *Section 55D*. *Conditional Approval for Primary Transplant Physician* below.

5A. Twelve-month Transplant Medicine Fellowship Pathway

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. Check to attest to the following

☐ *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 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. *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 to attest to the following

- ☐ *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.*

4. *The physician must have 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 a log that includes the date of procurement and Donor ID.

5. *The physician has observed **at least 3** pancreas 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.

6. ***Provide the following letters with the application:***

- A letter from director of the training program and supervising qualified pancreas transplant physician sent directly to the OPTN 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:
 - 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.
 - 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.

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 on a log that includes the date of transplant and medical record number or other unique identifier that can be verified by the OPTN. This recipient log should be signed by the program director, division chief, or department chair from the program where the physician gained this experience.

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 to attest to the following

- ☐ *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.*
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 on a log that includes the date of procurement and Donor ID.
 4. *The physician must have observed **at least 3** pancreas 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.

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

- A letter from the qualified pancreas transplant physician or surgeon who has been directly involved with the physician documenting the physician's experience and competence.
- A letter of recommendation from the primary physician and director at the transplant program last served by the physician outlining:
 - o The physician's overall qualifications to act as primary transplant physician.
 - o The physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations.
 - 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 they have gained in pancreas transplantation.

5C. Alternative Pathway for Predominantly Pediatric Programs

If a physician does not meet the requirements for primary physician through the transplant fellowship or clinical experience pathways as described above, transplant programs that serve predominantly pediatric patients may petition the MPSC in writing to consider the physician for primary transplant physician if the program can demonstrate that the following conditions are met:

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 Section 5 or the **clinical experience pathway**, as described in Section 55B. Clinical Experience Pathway above.

Provide documentation that supports equivalent training and experience, such as a log that includes the date of transplant and/or procurement, role of the surgeon, and medical record number or other unique identifier that can be verified by the OPTN.

3. ***Check to attest to the following***

- ☐ *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.*

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 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 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.

5D. Conditional Approval for Primary Transplant Physician

If the primary pancreas transplant physician changes at an approved pancreas transplant program, a physician can serve as the primary pancreas 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 **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 on a log that includes the date of transplant and medical record number or other unique identifier that can be verified by the OPTN. This log should be signed by the program director, division chief, or department chair from the transplant program where the experience was gained.

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 to attest to the following

- ☐ *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 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.*

3. Check to attest to the following

- ☐ *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.
This experience must be documented on a log that includes the date of procurement and Donor ID.
5. *The physician has observed **at least 3** pancreas transplants.*
This experience must be documented on a log that includes the transplant date and medical record number or unique identifier that can be verified by the OPTN.
6. ***Provide documentation*** that supports that the program has established and documented a ***consulting relationship*** with counterparts at another pancreas transplant program.
7. *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:
 - 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 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.

The 12-month conditional approval period begins on the initial approval date granted to the personnel change application, whether it is interim approval granted by the MPSC subcommittee, or approval granted by the full MPSC. The conditional approval period ends 12 months after the first approval date of the personnel change application.

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.

Instructions for Pediatric Component:

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

- If the surgeon is already the approved primary surgeon of the pancreas transplant program, complete number 1.
- If the surgeon is **NOT** already the approved primary surgeon of the pancreas transplant program, complete numbers 1 and 2. To demonstrate that the proposed individual meets the OPTN requirements for both primary pancreas surgeon and primary pediatric pancreas surgeon, check the box in number 2 to identify the desired pathway and complete Part 5 of this application.

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

- If the physician is already the approved primary physician of the pancreas transplant program, complete number 1.
- If the physician is **NOT** already the approved primary physician of the pancreas transplant program, complete numbers 1 and 2. To demonstrate that the proposed individual meets the OPTN requirements for both primary pancreas physician and primary pediatric pancreas physician, check the box in number 2 to identify the desired pathway and complete Part 6 of this application.

Part 7A: Primary Pediatric Pancreas Transplant Surgeon Requirements

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

Name	NPI # (optional)

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

- ☐ The **formal 2-year transplant fellowship pathway**, as described in Part 5, *Section 5* Program Director(s) (list all): above.
- ☐ The **pancreas transplant program clinical experience pathway**, as described in Part 5, *Section 55B. Clinical Experience Pathway* above.
- ☐ The **alternative pathway for predominantly pediatric programs**, as described in Part 5, *Section 55C. Alternate Pathway for Predominantly Pediatric Programs* above.

Part 7B: Primary Pediatric Pancreas Transplant Physician Requirements

1. **Name of Proposed Primary Pediatric Pancreas 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 **12-month pancreas transplant fellowship pathway**, as described in Part 6, *Section 5* above.
- ☐ The **clinical experience pathway**, as described in Part 6, *Section 55B. Clinical Experience Pathway* above.
- ☐ The **alternative pathway for predominantly pediatric programs**, as described in Part 6, *Section 55C. Alternative Pathway for Predominantly Pediatric Programs* above.
- ☐ The **conditional approval pathway**, as described in Part 6, *Section 55D. Conditional Approval for Primary Transplant Physician* above.

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 xx/xx/20xx. 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 5.79 hour(s) 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.