

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.

OPTN Representative

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| Printed Name | Signature | Email Address |
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Position _____

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Part 1: General Information

Name of Transplant Hospital: _____

OPTN Member Code (4 Letters): _____

Transplant Hospital Address (where transplants occur)

Street: _____ Ste: _____ Phone #: _____

City: _____ ST: _____ Zip: _____ Fax #: _____

Name of Person Completing Form: _____ Title: _____

Email Address of Person Completing Form: _____

Date Form is submitted to OPTN Contractor: _____

Part 2: 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.

| Name of Program Director(s) (list all): | New | Existing |
|---|--------------------------|--------------------------|
| _____ | <input type="checkbox"/> | <input type="checkbox"/> |
| _____ | <input type="checkbox"/> | <input type="checkbox"/> |
| _____ | <input type="checkbox"/> | <input type="checkbox"/> |
| _____ | <input type="checkbox"/> | <input type="checkbox"/> |

Include the resume/CV of each new individual listed.

Part 3: Primary Program Administrator

A primary program administrator is the identified administrative lead for the transplant program.

Complete this section only if you are updating the Primary Program Administrator position for the program.

Name of Primary Program Administrator:

Credentials:

Title at Hospital:

Phone Number:

Email:

Part 4: Primary Data Coordinator

A primary data coordinator is the identified data lead for the transplant program.

Complete this section only if you are updating the Primary Data Coordinator position for the program.

Name of Primary Data Coordinator:

Credentials:

Title at Hospital:

Phone Number:

Email:

Part 5: Primary Pancreas Transplant Surgeon Requirements

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

| Name | NPI # |
|------|-------|
|------|-------|

2. Check yes or no for each of the following. Provide documentation where applicable:

Yes No

- 2a. Does the surgeon have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction?

Provide a copy of the surgeon's resume/CV.

- 2b. Has the surgeon been accepted onto the hospital's medical staff, and is practicing on site at this hospital?

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

3. Certification. Check one and provide corresponding documentation:

- 3a. 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.

- 3b. 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 board certification, with the possibility of renewal for one additional 16-month period.

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

- 3c. The surgeon is without American Board of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, or the the Royal College of Physicians and Surgeons of Canada.

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

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

| Training and Experience | Approved Fellowship Program? Y/N | Date (MM/DD/YY) | | Transplant Hospital | Program Director | # of Pancreas Transplants as Primary | # of Pancreas Transplants as First Assistant | # of Pancreas Procurements as Primary or 1 st Assistant |
|----------------------------|----------------------------------|-----------------|-----|---------------------|------------------|--------------------------------------|--|--|
| | | Start | End | | | | | |
| Fellowship Training | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| 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 5Name 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.

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.*

This experience must be documented on a log that includes date of transplant, role of the surgeon, medical record number or other unique identifier, and the training program 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 training program 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 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 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
 - the individual's overall qualifications to act as 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 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.

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.

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 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 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 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
 - the individual's overall qualifications to act as 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 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.

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 must be equivalent to the **formal 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 on a log that includes the date of transplant and/or procurement, role of the surgeon, and Donor ID.

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.*
- 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.*

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.

Part 6: Primary Pancreas Transplant Physician Requirements

1. **Name of Proposed Primary Pancreas Transplant Physician (as indicated in Certificate of Assessment):**

| Name | NPI # |
|------|-------|
|------|-------|

2. **Check yes or no for each of the following. Provide documentation where applicable:**

Yes No

- 2a. Does the physician have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction? **Provide a copy of the physician's resume/CV.**
- 2b. Has the physician been accepted onto the hospital's medical staff, and is practicing on site at this hospital? **Provide documentation from the hospital credentialing committee that it has verified the physician's state license, board certification, training, and transplant continuing medical education, and that the physician is currently a member in good standing of the hospital's medical staff.**

3. **Certification. Check one and provide corresponding documentation:**

- 3a. The physician is currently certified in nephrology, 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.**
- 3b. 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. **The physician must be ineligible for American board certification. Provide an explanation why the individual is ineligible:**

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

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

| Training and Experience | Approved Fellowship Program? Y/N | Date (MM/DD/YY) | | Transplant Hospital | Program Director | # PA Patients Followed | | |
|----------------------------|----------------------------------|-----------------|-----|---------------------|------------------|------------------------|------|------|
| | | Start | End | | | Pre | Peri | Post |
| Fellowship Training | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| Experience Post Fellowship | | | | | | | | |
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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, if the primary pancreas transplant physician changes at an approved pancreas transplant program.

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. *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, 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 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:

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 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.

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
 - the individual's overall qualifications to act as primary transplant physician,
 - the individual's personal integrity and honesty, and
 - the individual's familiarity with and experience in adhering to OPTN obligations, and
 - 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.*
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 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 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.*
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
 - the individual's overall qualifications to act as 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 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

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* below or the **clinical experience pathway**, as described in *Section 55B. Clinical Experience Pathway* above. ***This experience must be documented on a log that includes the date of transplant and/or procurement, 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 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:

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.

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.

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 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.*

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.*

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.

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
 - 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.

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

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.

Part 7A: Primary Pediatric Pancreas Transplant Surgeon Requirements

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

| Name | NPI # |
|------|-------|
|------|-------|

2. Check yes or no for each of the following. Provide documentation where applicable:

Yes No

- 2a. Does the surgeon have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction?
Provide a copy of the surgeon's resume/CV.
- 2b. Has the surgeon been accepted onto the hospital's medical staff, and is practicing on site at this hospital?
Provide documentation from the hospital credentialing committee that it has verified the surgeon's state license, board certification, training, and transplant continuing medical education, and that the surgeon is currently a member in good standing of the hospital's medical staff.

3. Certification. Check one and provide corresponding documentation:

- 3a. 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.
- 3b. 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 board certification, with the possibility of renewal for one additional 16-month period.
Provide documentation supporting that training has been completed and certification is pending, which must include the anticipated date of board certification and where the surgeon is in the process to be certified.
- 3c. The surgeon is without 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.
- **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; and**

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

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

| Training and Experience | Approved Fellowship Program? Y/N | Date (MM/DD/YY) | | Transplant Hospital | Program Director | # of PA Transplants as Primary | # of PA Transplants as First Assistant | # of PA Procurements as Primary or 1 st Assistant |
|----------------------------|----------------------------------|-----------------|-----|---------------------|------------------|--------------------------------|--|--|
| | | Start | End | | | | | |
| Fellowship Training | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| 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 **formal 2-year transplant fellowship pathway**, as described in *Section 5* Name of Program Director(s) (list all): New Existing below.
- The **pancreas transplant program 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.*

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

2. *The surgeon 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 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 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
 - the individual's overall qualifications to act as 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 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.

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.

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 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 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
 - the individual's overall qualifications to act as 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 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.

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 must be equivalent to the **formal 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 on a log that includes the date of transplant and/or procurement, the role of the surgeon, and medical record number or other unique identifier.

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.*
- 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.

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.

Part 7B: Primary Pediatric Pancreas Transplant Physician Requirements

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

| | |
|------|-------|
| Name | NPI # |
|------|-------|

2. Check yes or no for each of the following. Provide documentation where applicable:

Yes No

- 2a. Does the physician have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction? **Provide a copy of the physician's resume/CV.**
- 2b. Has the physician been accepted onto the hospital's medical staff, and is practicing on site at this hospital?

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

3. Certification. Check one and provide corresponding documentation:

- 3a. The physician is currently certified in nephrology, 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.
- 3b. 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.
The physician must be ineligible for American board certification. Provide an explanation why the individual is ineligible:

-
- Provide a plan for continuing education that is comparable to American board maintenance of certification; and
 - Provide at least 2 two letters of recommendation from directors of designated transplant programs not employed by the applying hospital that address
 - o why an exception is reasonable,
 - o the individual's overall qualifications to act as a primary pancreas transplant physician,
 - o the individual's personal integrity and honesty,

- o the individual's familiarity with and experience in adhering to OPTN obligations and compliance protocols, and*
- o any other matters judged appropriate.*

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

| Training and Experience | Approved Fellowship Program? Y/N | Date (MM/DD/YY) | | Transplant Hospital | Program Director | # PA Patients Followed | | |
|----------------------------|----------------------------------|-----------------|-----|---------------------|------------------|------------------------|------|------|
| | | Start | End | | | 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 *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, if the primary pancreas transplant physician changes at an approved pancreas transplant program.

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. *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, 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 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:

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 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.

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
 - the individual's overall qualifications to act as primary transplant physician,
 - the individual's personal integrity and honesty, and
 - the individual's familiarity with and experience in adhering to OPTN obligations, and
 - 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..*

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 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 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.*

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,
 - 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 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

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. 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 on a log that includes the date of transplant and/or procurement and medical record number or other unique identifier.

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.*

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.

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.

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.*

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.

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

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.