

OPTN Membership Application for Islet Transplant Programs

CERTIFICATION

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

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

OPTN Representative

Printed Name

Signature

Email Address

Instructions:

Complete **Parts 1 and 4** of the application for all applications.

Check to select one of the options below

- Application for program requiring a primary surgeon and primary physician*
 - To propose a **primary surgeon** who is currently the approved primary surgeon of the pancreas program, complete **Parts 5 and 7** of this application.
 - To propose a **primary surgeon** who is **NOT** currently the approved primary surgeon of the pancreas program, complete **Parts 5 and 7** of this application, and **Parts 2, 3, and 5** of the **pancreas program application**.
 - To propose a **primary physician** who is currently the approved primary physician of the pancreas program, complete **Parts 6 and 7** of this application.
 - To propose a **primary physician** who is **NOT** currently the approved primary physician of the pancreas program, complete **Parts 6 and 7** of this application, and **Parts 2, 3, and 6** of the **pancreas program application**.
 - If the islet program is not located at a hospital approved as a designated pancreas transplant program, complete **Part 8** to demonstrate that the additional criteria are met.

- Application for program requiring a clinical leader*
 - To propose a **clinical leader**, complete **Parts 2, 3, 9, and 10** of this application.
 - If the islet program is not located at a hospital approved as a designated pancreas transplant program, complete **Part 11** to demonstrate that the additional criteria are met.

Part 1: General Information

Name of Transplant Hospital: _____

OPTN Member Code (4 Letters): _____

Transplant Hospital Address (where transplants occur)

Street: _____ Suite: _____

City: _____ State: _____ Zip: _____

Islet Transplant Program Phone #: _____

Islet Transplant Program Fax #: _____

Name of Person Completing Form: _____ Title: _____

Email Address of Person Completing Form: _____

Date Form is submitted to OPTN Contractor: _____

Part 2: Certificate of Assessment

For programs with a clinical leader

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 **clinical leader** is responsible for ensuring the operation and compliance of the program according to the requirements set forth in the OPTN Bylaws. The transplant hospital must notify the OPTN Contractor immediately if at any time the program does not meet these requirements.

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.

- *For any surgeon or physician indicated as 'Clinical Leader' that isn't already the approved clinical leader 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.*

Part 3: Program Coverage Plan

For programs with a clinical leader

The program director, along with the clinical leader, 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 the clinical leader, expert medical personnel and additional clinicians who have been credentialed by the transplant hospital to provide transplant services to the program.

An islet transplant program must inform its patients if the level of program staffing may create instances where potential unavailability of certain staff 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 Program Coverage

Yes No

Is this a single clinician program?

If yes, provide a copy of the patient notice or protocol for providing patient notification.

Does the transplant program have personnel 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 an islet clinical leader or additional clinician readily available in a timely manner to facilitate organ acceptance, procurement, and transplantation?

*Is the **clinical leader** designated as the clinical leader at more than one transplant hospital?*

If yes, answer the question below.

Yes No

*Do you have additional clinicians 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 **clinical leader onsite** full-time at this transplant hospital?*

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

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)

An islet 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 Islet Transplant Surgeon Requirements

The program must have on site a qualified surgeon who is designated as the primary pancreatic islet transplant surgeon and meets the requirements for pancreas transplant surgeon defined in these Bylaws.

1. **Name of Proposed Primary Islet Transplant Surgeon:**

Name

NPI # (optional)

2. **Check to select one of the options below:**

- The proposed primary surgeon is currently the approved primary surgeon of the pancreas program.
- The proposed primary surgeon is **NOT** currently the approved primary surgeon of the pancreas program.

Complete Parts 3, 4, and 5 of the pancreas program application.

Part 6: Primary Islet Transplant Physician Requirements

The program must have on site a qualified physician who is designated as the primary pancreatic islet transplant physician and meets the requirements for pancreas transplant physician defined in these Bylaws.

1. **Name of Proposed Primary Islet Transplant Physician:**

Name

NPI # (optional)

2. **Check to select one of the options below:**

- The proposed primary physician is currently the approved primary physician of the pancreas program.
- The proposed primary physician is **NOT** currently the approved primary physician of the pancreas program.

Complete Parts 3, 4, and 6 of the pancreas program application.

Part 7: Islet Transplant Program Additional Requirements

For programs with a primary surgeon and physician

Select yes or no for the following

Yes No

- Is the islet transplant program at a hospital that has approval of a designated pancreas transplant program?*
If the answer is no, complete Part 8 of the application below.

Transplant Facilities

The program must demonstrate that the required resources and facilities are available.

Check to attest to the following. Provide documentation where applicable.

- The program has adequate clinical and laboratory facilities for islet transplantation as defined by current Food and Drug Administration (FDA) regulations.*

Provide documentation that supports this claim.

- The required Investigational New Drug (IND) application is in effect as required by the FDA.*

Provide documentation that supports this claim.

Islet Isolation

Select yes or no for the following

Yes No

- Are pancreatic islets isolated at a location other than the transplant facility?*

If yes, check to attest to the following, and provide documentation showing collaboration between the program and the facility where pancreatic islets are isolated.

- The facility where pancreatic islets are isolated has an FDA Investigational New Drug (IND) application in effect.*

Medical Personnel

Check to attest to the following

Note: Any individual, including the primary surgeon or physician, may fill one or more of the expert medical personnel positions below. "Adequate access" is defined as having an agreement with another institution for access to employees with the expertise described above.

- The program has a collaborative relationship with a physician qualified to perform portal vein cannulation under direction of the transplant surgeon.*
- The program has on site or adequate access to a board-certified endocrinologist.*

- The program has on site or adequate access to a physician, administrator, or technician with experience in compliance with FDA regulations.*
- The program has on site or adequate access to a laboratory-based researcher with experience in pancreatic islet isolation and transplantation.*

Provide a list of these individuals with the application to show proof of collaboration.

Part 8: Programs Not Located at an Approved Pancreas Transplant Program

For programs with a primary surgeon and physician

A program that meets all requirements for a designated pancreatic islet transplant program but is not located at a hospital approved as a designated pancreas transplant program may qualify as a pancreatic islet transplant program if the following additional criteria are met:

1. The program demonstrates a documented affiliation with a designated pancreas transplant program, including on-site admitting privileges for the primary pancreas transplant surgeon and physician.

Name of affiliated transplant hospital: _____

Provide hospital credentialing letters for the primary pancreas transplant surgeon and physician from the affiliated hospital.

2. The program is committed to and has the ability to counsel patients about all their options for the medical treatment of diabetes.

Provide documented protocols that support this claim.

3. The program demonstrates availability of qualified personnel to address pre-, peri-, and post-operative care issues regardless of the treatment option ultimately selected.

Provide documentation that supports this claim.

An informal discussion with the MPSC is also required.

Part 9: Islet Transplant Program Clinical Leader Requirements

1. Name of Proposed Islet Program Clinical Leader (as indicated in Part 2: Certificate of Assessment):

Name	NPI # (optional)
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2. Check to attest to each of the following. Provide documentation where applicable:

- The clinical leader 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 clinical leader's medical license or resume/CV to show proof of this requirement.

- The clinical leader 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 clinical leader's state license, board certification, training, and transplant continuing medical education, and that the clinical leader is currently a member in good standing of the hospital's medical staff.

3. The clinical leader has been directly involved in the management and care of **at least 6** islet transplant patients, with the management and care of **at least one** islet transplant patients having occurred in the last two years. Of the 6 islet transplant patients, **at least one** must be an **allogeneic** islet transplant patient.

This experience must be documented in a log that includes the date of the care provided, the category of care provided as described above, whether the patient was an autologous or allogeneic islet transplant patient, and the patient's medical record number or other unique identifier. This log should be signed by the program director, division chief, or department chair from the program where the experience was gained.

4. The clinical leader has maintained a current working knowledge of all aspects of islet transplantation, defined as direct involvement in islet transplant patient care.

Check all that apply

- The clinical leader has been directly involved with selecting donors.
- The clinical leader has been directly involved with evaluating islets.
- The clinical leader has been directly involved with accessing the portal vein for islet transplant procedures.
- The clinical leader has been directly involved with overseeing the islet infusion.
- The clinical leader has been directly involved with managing immunosuppression.

5. *The clinical leader observed or performed at least three islet isolations, of which at least one must be an allogeneic islet isolation.*

This experience must be documented in a log that includes the date of the isolation procedure, whether the isolation was observed or performed, whether the isolation was for an autologous or an allogeneic islet transplant and the patient's medical record number or other unique identifier for autologous transplant use or donor ID for allogeneic transplant use. This log should be signed by the program director, division chief, or department chair from the program where the isolations were observed or performed.

6. *The clinical leader has a background in transplantation medicine, immunosuppression management, beta cell biology, or endocrinology.*

This background must be demonstrated in documentation submitted to the OPTN contractor of a clinical fellowship lasting at least 6 months in transplantation medicine, transplantation surgery, immunosuppression management, beta cell biology, or endocrinology.

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

- A letter from the director or chair of the islet program or the director or chair of another islet transplant program where the physician or surgeon has served outlining:
 - o the clinical leader's overall qualifications to act as islet transplant program clinical leader.
 - o the clinical leader'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 others affiliated with any islet transplant program previously served by the individual, at its discretion.
- A letter from the proposed clinical leader that details the training and experience the individual has gained in islet transplantation.

8. ***If the clinical leader is a surgeon, check one and provide corresponding documentation:***

The clinical leader is currently certified by the American Board of Urology, the American Board of Osteopathic Surgery, or the Royal College of Physicians and Surgeons of Canada.
Provide a copy of the clinical leader's current board certification.

The clinical leader has just completed training and is pending certification by the American Board of Urology, the American Board of Osteopathic Surgery, or the Royal College of Physicians and Surgeons of Canada. Therefore, the clinical leader is requesting conditional approval for 24 months to allow time to complete board certification, with the possibility of renewal for one additional 24-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 clinical leader is in the process to be certified.

- The clinical leader is without certification from American Board of Urology, the American Board of Osteopathic Surgery, or the Royal College of Physicians and Surgeons of Canada.

If this option is selected:

- **The clinical leader 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 clinical leader's overall qualifications to act as a clinical leader in islet transplantation,
 - 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.

9. **If the clinical leader is a physician, check one and provide corresponding documentation:**

- The clinical leader is currently certified nephrology, endocrinology, immunology, or diabetology by the American Board of Internal Medicine, the American Board of Pediatrics, of the Royal College of Physicians and Surgeons of Canada.

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

- The clinical leader is without certification in nephrology, endocrinology, immunology, or diabetology by the American Board of Internal Medicine, the American Board of Pediatrics, of the Royal College of Physicians and Surgeons of Canada.

- **The clinical leader 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 clinical leader obtains 60 hours of Category I continuing medical education (CME) credits.
 - o the clinical leader 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 individual's overall qualifications to act as a clinical leader in islet transplantation,***
 - o the individual's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.***
 - o any other matters judged appropriate.***

Part 10: Islet Transplant Program Additional Requirements

For programs with a clinical leader

Select yes or no for the following

Yes No

- Is the islet transplant program at a hospital that has approval of a designated pancreas, kidney, liver, or intestine transplant program?
If the answer is no, complete Part 11 of the application below.*

Transplant Facilities

The program must demonstrate that the required resources and facilities are available.

Check to attest to the following. Provide documentation where applicable.

- The program has adequate clinical and laboratory facilities for islet transplantation as defined by current Food and Drug Administration (FDA) regulations.
Provide documentation that supports this claim.*
- The required Investigational New Drug (IND) application or approved Biologics License Application (BLA) is in effect as required by the FDA.
Provide documentation that supports this claim.*
- The program has a letter of agreement or contract with the transplant hospital's OPO that specifically indicates it will provide the pancreas for islet cell transplantation.
Provide the letter of agreement or contract with the OPO.*

Medical Personnel

Check to attest to the following. Answer in the spaces provided below.

Note: Any individual, including the clinical leader, may fill one or more of the expert medical personnel positions below. "Adequate access" is defined as having an agreement with another institution for access to employees with the expertise described above.

- The program has a pancreas, kidney, liver, or intestine transplant surgeon on site.*
- The program has a surgeon or interventional radiologist who has performed **at least three** portal vein access procedures on site.*
- The program has a physician to handle immunosuppression who has managed **at least six** immunosuppression management cases on site.*
- The program has an endocrinologist or physician on site who is experienced in metabolic studies on site.*

- The program has on site or adequate access to a person with experience in compliance with FDA regulations.*
- The program has on site or adequate access to a diabetes educator.*
- The program has on site or adequate access to a scientist with experience in islet quality assessment.*

Islet Isolation

Select yes or no for the following

Yes No

- Are islets isolated at a location other than the transplant facility?
If yes, check to attest to the following, and provide documentation showing collaboration between the program and the facility where islets are isolated.*
 - The facility where islets are isolated has an FDA Investigational New Drug (IND) or approved BLA application in effect.*

Part 11: Programs Located at a Hospital that does not have an Approved Pancreas, Kidney, Liver, or Intestine Transplant Program

For programs with a clinical leader

A program that meets all requirements for a designated pancreatic islet transplant program but is not located at a hospital approved as a designated pancreas, kidney, liver, or intestine transplant program may qualify as a pancreatic islet transplant program if the following additional criteria are met:

1. The program demonstrates a documented affiliation with a designated pancreas, kidney, liver, or intestine transplant program, including on-site admitting privileges for the pancreas, kidney, liver, or intestine program's primary transplant surgeon and physician.

Name of affiliated transplant hospital: _____

Provide hospital credentialing letters for the primary pancreas transplant surgeon and physician from the affiliated hospital.

2. The program is committed to and has the ability to counsel patients about all their options for the medical treatment of diabetes.

Provide documented protocols that support this claim.

3. The program demonstrates availability of qualified personnel to address pre-, peri-, and post-operative care issues regardless of the treatment option ultimately selected.

Provide documentation that supports this claim.

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 07/31/2023. 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 5 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.