

Part 4: Facilities - Pancreas Islet Transplant Program

This section must be completed when applying for a new program or reactivating an existing program.

1. Indicate below the anticipated start date that the transplant program will become operational.

[Insert detailed response here. Table will expand automatically]
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2. Does this hospital presently have an OPTN approved pancreas transplant program?

Yes	
No	

The program must document adequate clinical and laboratory facilities for pancreatic islet transplantation as defined by current Food and Drug Administration (FDA) regulations. The program must also document that the required Investigational New Drug (IND) application is in effect as required by the FDA.

Provide the following:

- Documentation that verifies that the program has adequate clinical and laboratory facilities for pancreatic islet transplantation as defined by the current regulations provided by the Food and Drug Administration (FDA).
- Copy of the transplant hospital's IND application form and a copy of the letter from the FDA that verifies receipt of the application.
- Copy of written documentation provided by the FDA that confirms the active status of the IND (if received by transplant hospital at the time of OPTN application submission).
- Letter of agreement or contract with the transplant hospital's OPO that specifically indicates it will provide the pancreas for islet cell transplantation.
- If islet cells are isolated and processed at a location other than the transplant facility, provide the name(s) of the processor(s) and any available arrangement documentation.

Part 5: Supporting Personnel

1. Provide a C.V. for the physician qualified to perform portal vein cannulation under direction of the transplant surgeon.

Name of designated physician:

2. Verify that the program has access to the personnel listed below.

	Yes	No
A board-certified endocrinologist		
A physician, administrator, or technician with experience in compliance with FDA regulations		
A laboratory-based researcher with experience in pancreatic islet isolation and transplantation		

Part 6: Programs Not Located at an Approved Pancreas Transplant Hospital

Refer to the OPTN Bylaws for the requirements regarding a designated pancreas islet transplant program that is not located in a hospital with an approved pancreas transplant program.

1. There must be an affiliation with an OPTN approved pancreas transplant program, including on site admitting privileges at this applicant hospital for the affiliated hospital's primary pancreas transplant surgeon and physician. Provide a hospital credentialing letter for the primary pancreas transplant surgeon and physician at the applicant hospital.

Name of affiliated transplant hospital:

- a) Designated primary pancreas transplant surgeon.

Name:

Percentage of time on site:

- b) Designated primary pancreas transplant physician.

Name:

Percentage of time on site:

2. Describe the availability of the above qualified personnel to address pre-, peri-, and post-operative care issues regardless of the treatment option ultimately selected.

[Insert response here, table will expand automatically]

3. Provide a copy of the written protocols that demonstrate the program's commitment and ability to counsel patients regarding all their options for appropriate medical treatment for diabetes.