ATTACHMENT I
TO APPENDIX B OF UNOS BYLAWS

Designated Transplant Program Criteria

XII. Additional Requirements for Pancreatic Islet Transplantation. The following provisions apply to all pancreatic islet transplantation programs. Pancreatic islet transplantation programs approved under any previous criteria must submit an application documenting their compliance with the criteria below. For pancreatic islet transplantation, programs must meet all of the following criteria in addition to the criteria set forth in Sections I - X above:

A. Approved Pancreas Transplant Program – The program must be located at a medical center approved under these Bylaws to perform whole pancreas transplantation, or meet the requirements for an exception to this criterion as set forth in this Section XI(F) below.

B. Reporting – The program must submit data to UNOS through use of standardized forms. Data requirements include submission of information on all deceased and living donors, potential transplant recipients, and actual transplant recipients. Pending development of standardized data forms for pancreatic islet transplantation, the program must provide patient logs to UNOS every six months and on an annual basis, reporting transplants performed, by patient name, social security number, date of birth, and donor identification number, as well as whether patient is alive or dead, and whether the pancreas was allocated for islet or whole organ transplantation. The logs shall be cumulative. Additionally, for each donor pancreas allocated to the program for islet transplantation, the program must report to UNOS whether the islets were used for clinical islet transplantation and, if not, why and their ultimate disposition, together with such other information as requested on the Pancreatic Islet Donor Form.

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

D. Radiology Expertise/Ancillary Personnel – The program must have a collaborative relationship with a physician qualified to canulate the portal system under direction of the transplant surgeon. It is further recommended that the program have on site or adequate access to:

(1) A board-certified endocrinologist.

(2) A physician, administrator, or technician with experience in compliance with FDA regulations, and

(3) A laboratory-based researcher with experience in pancreatic islet isolation and transplantation.

Adequate access is defined by an agreement of affiliation with counterparts at another institution who employ individuals with the expertise described above.

E. Islet Isolation – Pancreatic islets must be isolated in a facility with an FDA IND application in effect, with documented collaboration between the program and such facility.

F. Programs Not Located at an Approved Pancreas Transplant Program – A program that meets all requirements for a pancreatic islet transplant program set forth in these Bylaws, including, without limitation, requirements applicable generally for designated transplant program status and without regard to organ specificity, with the sole exception that the program is not located at a medical center approved under these Bylaws to perform whole pancreas transplantation, may nevertheless qualify as a pancreatic islet transplant program if the following additional criteria are met to the satisfaction of the Membership and Professional Standards Committee and Board of Directors:

(1) The program demonstrates a documented affiliation relationship with a UNOS approved pancreas transplant program, including on-site admitting privileges for the primary whole pancreas transplant surgeon and physician,

(2) The program provides written protocols demonstrating its commitment and ability to counsel patients regarding all their options for appropriate medical treatment for diabetes, and

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

A preliminary interview with the Membership and Professional Standards Committee shall be required.