Clinical Islet Transplantation (CIT) Consortium
Site Qualification Criteria

Participation in the clinical protocols conducted by the Clinical Islet Transplantation (CIT) consortium will be limited to centers with a demonstrated track record of robust clinical success. These candidate centers will need to demonstrate a willingness to standardize their islet manufacturing process to comply with the manufacturing protocol of the CIT Group. Specific criteria for qualification are listed below.

1. Criteria for participation in CIT: Centers that locally manufacture and transplant islets

All CIT centers must demonstrate a strong track record of success in both islet preparation and in clinical transplantation. A total accrued experience of at least 8 consecutive islet transplant recipients (either islet-alone or islet after-kidney) is required. Experience will be accrued for transplants occurring any time after January 2000, providing an opportunity for a relatively new center to apply. Funding for these qualifying transplants would need to be derived external to the NIH Consortium effort.

Of the 8 consecutive subjects transplanted, 7 must have demonstrated persistent C-peptide secretion at 1, 3 and 6 months post first transplant (>0.5ng/ml), and 5 of the 8 must have achieved insulin independence for at least 30 days, after one, two or three islet infusions; at the end of the 30 day period, the HbA1c must be <7.0% or have decreased from baseline by ≥2.5% within 2 months of transplant. In addition, sites must have adequate manufacturing facilities as determined by an evaluation carried out by an independent GMP consultant working under contract to the CIT consortium and the CIT CMC Subcommittee.

2. Criteria for centers that receive islets from a CIT manufacturing site

If islets are shipped from a CIT islet manufacturing site, the following criteria would apply:

Of 3 consecutive patients transplanted at the clinical site, all must demonstrate persistent C-peptide secretion at 1, 3 and 6 months post transplant, and 2 of 3 patients must demonstrate insulin independence for at least 30 days, after one, two or three islet infusions; at the end of the 30 day period, the HbA1c must be <7.0% or have decreased from baseline by ≥2.5% within 2 months of transplant.

3. Additional criteria for sites participating in CIT-06 only: Centers that locally manufacture and transplant islets

a. An Endocrinologist team must be available for adequate subject care.
b. Clinical islet transplant centers must be a member of an active, UNOS approved islet transplant collaboration or geographically proximate to a cooperating UNOS approved islet transplant center.
c. Clinical islet transplant centers must be able to recruit the subject population by providing a description of their OPO and the number of pancreatic and kidney donors.

Version 3.2
January 10, 2008