APPLICATION FORM

PILOT STUDY OF ISLET TRANSPLANT IN THE EYE OF LEGALLY BLIND T1D PATIENTS

INSTRUCTIONS:

This application and the information you provide will be used to determine if you qualify to participate in a research study to evaluate the safety and efficacy of islet transplant in the eye of legally blind Type 1 diabetes patients. We will maintain your information in a secure location and only our research staff will access it. This information will not be reused or disclosed to any other person or entity, except as required by law. The information you will provide will be stored in our files for a period not to exceed ten (10) years. If you give us permission, even if you are not eligible, we would like to keep your information in our files.

CONSENT TO ALLOW TO BE CONTACTED FOR CLINICAL TRIALS AT THE DIABETES RESEARCH INSTITUTE:

I,_____(Print Name) agree to be contacted by the Clinical Cell Transplant Program (CCTP) team regarding the pilot trial on islet transplant in the eye or other future clinical trials for which I may be eligible.

I also agree and consent that my name and contact information may be provided by the CCTP to other departments at the Diabetes Research Institute for the purpose of clinical trial information and/or eligibility screening.

Signature:	**Date:**	**Phone #**

Please complete the entire application form and mail it to us at:

Clinical Cell Transplant Program
Diabetes Research Institute
PO Box 016960 (R134)
Miami, FL 33101

You may fax a copy of the completed form to **305-243-1058,** but we ask that you also mail the original form to us. Be sure to keep copies for your records.

Please read all questions carefully and complete *ALL* the pages. Print clearly and do not leave any blanks. Write N/A for any questions that do not apply.

Applicant's Personal Information (Please print clearly).			
1.Name (Last, MI, First)	2.Date of Birth (MM/DD/YY)	3.Age	4.Gender ☐ Male ☐ Female
5.Street Address		6.Occupation	
7.City	8.State/Prov	9.Zip/Postal Code	10.E-mail Address
11.Home Telephone	12.Work Telephone	13.Cell Phone Number	14.Fax Number
15.Emergency Contact	16.Telephone	17.Relationship	18.How did you hear about us?

Complete this section (about yourself) *if you are entering the information for the applicant*.		
19.Name (Last, First)		
20.Address, City, State, ZIP		
21.Telephone	22.Email Address	23.Relationship

Diabetes Information		
24. Diabetes: ☐ Type 1 ☐ Type 2		
25.Date Diagnosed: Month/Year	26. Age at Diagnosis	27. Diabetes Duration _____ Years
28. Current Weight: _____lbs._____kg.	29.Your height: _____ft._____in.	

Hypoglycemia
30. Do you suffer from frequent low blood sugar that result in loss of consciousness? ☐ Yes ☐ No
31. Do you have hypoglycemia unawareness? (Inability to sense when blood sugar is low) ☐ Yes ☐ No
Hypoglycemia Score (recall)
32. Have you ever needed help from someone else to **recognize** a low blood sugar? ☐ Yes ☐ No 32.1 If you answered, "yes" to the previous question, how many times has this occurred in the last 12 months? _____
33. Have you ever needed help from someone else to **treat** a low blood sugar? ☐ Yes ☐ No 33.1 If you answered, "yes" to the previous question, how many times has this occurred in the last 12 months? _____
34. Have you ever needed **glucagon** injections to treat a low blood sugar? ☐ Yes ☐ No 34.1 If you answered, "yes" to the previous question, how many times has this occurred in the last 12 months? _____
35. Have you ever been taken to an **Emergency Room** or had an **ambulance** called for you in order to treat a low blood sugar? ☐ Yes ☐ No 35.1 If you answered, "yes" to the previous question, how many times has this occurred in the last 12 months? _____

Diabetes Management

36.Are you under the care of an endocrinologist or diabetes specialist? ☐ Yes ☐ No

36.1 If yes, how many times have you visited him/her in the past year? _____

37.Has your endocrinologist measured your C-peptide recently? ☐ Yes ☐ No

37.1 If you have answered, "yes" to the previous question please provide:

Fasting C-peptide result:_____Date:_____

38. What was your last HBA1C result?_____Date:_____

39. How many times a day do you test your blood sugars? _____

40. How do you administer your Insulin? ☐ Insulin Injections ☐ Insulin Pump

41. If you use insulin injections, please answer the following questions?

41.1 What is the average BASAL INSULIN that you require per day? _____

41.2 What is the average BOLUS INSULIN that you use per day? _____

42. Please Circle ***all*** the insulin preparations that you are currently using:

A) Rapid acting	B) Short acting	C) Intermediate acting
•Humalog/Lispro •Novolog/Aspart •Apidra/Glulisine	•Regular •Humulin R •Novolin R	•NPH •Humulin N •Novolin N

D) Long acting	E) Mixed Insulin	F) Other: (Write in if not listed)
•Lantus/Glargine •Toujeo/Glargine •Tresiba/Degludec •Levemir/Detemir	•50/50 •70/30 •72/25	•_____ •_____ •_____

In the tables below, list any significant illnesses other than diabetes and/or major surgeries you have had. *(Attach additional page, if necessary).*

Medical History Please list any relevant medical problems not listed in the previous sections of the form.

Medical Diagnosis	**Onset Date**	**Current Status** **	**Date Resolved**	**Treatment** (Medication/Surgery etc.)

** Choose from the following options: Active, Stable, Stable/treated, Intermittent, or Resolved.

Surgical History (Please print clearly)

Surgery	**Date**	**Outcome**	**Complications**

Additional Medical / Surgical Background		
43. Do you have a history of allergies with fish/shellfish?	☐ Yes	☐ No
44. Do you have a bleeding or blood clot problem?	☐ Yes	☐ No
46.1 If you answered, "yes" to the previous question, please explain: _____		
45. Have you ever had any type of cancer, including skin cancer?	☐ Yes	☐ No
45.1 If you answered, "yes" to the previous question, please explain: _____		
46. Have you ever had an organ transplant?	☐ Yes	☐ No
46.1 If you answered, "yes" to the previous question, what organ (s)? _____		

In the table below, list any medications you are currently taking *(attach additional page, if necessary*).

Current Medications (please print clearly)								
Drug Name	Trade Name	Date Started	Dose	Units mg, etc.	Route	Fre-quency	Indication/Reason	Prescribed by

47. List known allergies to medications: _____

Referral Information (please print clearly)
48. How did you find out about this research trial? ☐ Doctor ☐ Newspaper ☐ Friend ☐ DRI website ☐ Other patient ☐ Magazine ☐ Other
49. Are you currently participating in any other research trial investigating a new drug? ☐ Yes ☐ No

Endocrinologist / Diabetologist (please print clearly)			If Referring Physician check here ☐
50. Name (Last, MI, First include MD, ARNP, PHD etc.)		51. ☐ Family practitioner ☐ Internist ☐ Endocrinologist/Diabetologist	
52. Address			
53. City	54. State/Province	55. Zip/Postal Code	56. E-Mail Address (if known)
57.Work Telephone (if outside the US, include country code)		58.Fax Number	

I, print your name here, understand that by completing this form and returning it to the Diabetes Research Institute, I am granting the Diabetes Research Institute permission to use the information contained in this form for research purposes.

Your records and results will be kept confidential to the extent permitted by law and according to current HIPAA guidelines. The Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS) may request to review and retain copies of these research records.

SIGNATURE: _____ **DATE:** _____