



ISLET TRANSPLANT APPLICATION FORM

INSTRUCTIONS:

This application and the information you provide will be used to determine if you are able to participate in an islet transplant trial at the Diabetes Research Institute. We will maintain your information in a secure location and it will be accessed only by our research staff. 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 BE CONTACTED FOR CLINICAL TRIALS AT THE DIABETES RESEARCH INSTITUTE:

I, _____ (Print Name) agree to be contacted by the Clinical Islet Transplantation Program (CITP) team regarding 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 CITP 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 Islet 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.

Diabetes Research Institute

1450 NW 10th Avenue, Miami, FL 33136

Telephone: 305-243-5321 or 305-243-5557

Fax 305-243-1058

E-mail: Islet@med.miami.edu

ISLET TRANSPLANT CANDIDATE INFORMATION FORM

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: <input type="checkbox"/> Male <input type="checkbox"/> 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			
19. Name (Last, First)			
20. Address, City, State, ZIP			
21. Telephone	22. Email Address	23. Relationship	
Social Information			
24. Marital Status: <input type="checkbox"/> Never married <input type="checkbox"/> Married <input type="checkbox"/> Separated <input type="checkbox"/> Divorced <input type="checkbox"/> Widowed			
25. Ethnic/Race Background: <input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Asian <input type="checkbox"/> Black or African American <input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Native Hawaiian or other Pacific Islander <input type="checkbox"/> White or Caucasian			
26. Current weight: _____ lbs. Your height: _____ ft. _____ in.			
27. Are you a current smoker? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, enter number of cigarettes per day _____ and for how long you have been smoking _____ years			
28. Do you have a history of smoking? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, how many cigarettes per day did you smoke? _____ How many years did you smoke? _____ What year did you stop smoking? _____			
29. Do you consume alcoholic beverages? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, enter the average number of alcoholic beverages you drink per week _____ Type of beverage _____			
30. Are you of childbearing age? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, are you currently: <input type="checkbox"/> pregnant <input type="checkbox"/> breast feeding List any method of birth control you currently use: _____			

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Diabetes Information:

31. Diabetes: <input type="checkbox"/> Type 1 <input type="checkbox"/> Type 2	32. Date Diagnosed: Month/year_____	33. Age at Diagnosis: _____	34. Diabetes Duration: _____ years
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History of Diabetes Complications of the eyes, kidneys, nerves, cardiovascular & DKA

35. Do you have or have you ever had diabetic eye disease (retinopathy)? YES NO

If you answer "no" to the previous question, go to question #36.
If you answered "yes" to the previous question, please answer the following questions:

35.a. Which eye is/was affected? Left Right Both

35.b. What kind of retinopathy do you have? Active proliferative Stable proliferative Non-proliferative

35.c. Have you ever had eye surgery (laser therapy or vitrectomy)? YES

NO If yes, which eye?_____Date of procedure: _____

36. Do you have diabetic kidney disease (nephropathy)? YES NO

If you answer "no" to the previous question, go to question #37.
If you answered "yes" to the previous question, please answer the following questions:

36.a. What kidney condition do you have? Elevated creatinine Microalbuminuria
 Moderate to severe proteinuria Kidney failure

36.b. Are you on dialysis? YES NO

36.c. Have you had a kidney transplant? YES NO

If Yes, date: _____Hospital/Surgeon: _____

37. Do you have diabetic nerve damage (neuropathy)? YES NO

37.a. If you answered "yes" to the previous question, please check all that apply:

- Numbness in hands/feet Sensory loss dizziness on standing rapid heartbeat at rest
- Nausea/Vomiting Diarrhea Bloating Problems with sexual function Other: _____

38. Do you have diabetic damage of the blood vessels (cardiovascular disease)? YES NO

38.a. If you answered "yes" to the previous question, please check all (treated and untreated) that apply:

- High blood pressure High cholesterol High triglycerides Low HDL High LDL
- Heart (heart attack/angina) Stroke/TIA Leg pain when walking (PVD/ Claudication)
- Bypass surgery Amputation (specify site): _____ Other: _____

39. Do you have unstable diabetes that has failed to respond to intensive insulin therapy as judged by an Endocrinologist or Diabetologist? YES NO

40. . Have you ever had diabetic Ketoacidosis (DKA) or high blood sugar with ketones requiring hospitalization? YES NO

40.a. If you answered "yes" to DKA, how many times in the past year? _____

History of Diabetes Complications, Hypoglycemia

41. Do you suffer from frequent low blood sugars that result in loss of consciousness? YES NO

42. Do you have hypoglycemia unawareness? (inability to sense when your blood sugar is low) YES NO

Hypoglycemia score (recall)

43. Have you ever needed help from someone else to **recognize** a low blood sugar? YES NO

43.a. If you answered, "yes" to the previous question, how many times has this occurred in the last 12 months? _____

44. Have you ever needed help from someone else to **treat** a low blood sugar? YES NO

44.a. If you answered, "yes" to the previous question, how many times has this occurred in the last 12 months? _____

45. Have you ever needed **glucagon** injections to treat a low blood sugar? YES NO

45.a. If you have answered, "yes" to the previous question, how many times has this occurred in the past 12 months? _____

46. 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

46.a. If you have answered, "yes" to the previous question, how many times has this occurred in the past 12 month? _____

Clarke Hypoglycemia Survey:

47. Check category that best describes you (check one only)

- I always have symptoms when my blood sugar is low.
- I sometimes have symptoms when my blood sugar is low.
- I no longer have symptoms when my blood sugar is low.

48. Have you lost some of the symptoms that used to occur when your blood sugar was low?

- Yes No

49. In the past 6 months, how often have you had hypoglycemia episodes (low blood sugar) where you felt confused, disoriented, or lethargic and were unable to treat yourself (required assistance from another person)?

- Never Once or twice Every other month Once a month More than once a month

50. In the past 12 months, how often have you had hypoglycemia episodes (low blood sugar) where you were unconscious or had a seizure and needed glucagon injection or intravenous glucose?

Circle one 0 1 2 3 4 5 6 7 8 9 10 11 12 or more

51. How often, in the last month, have you had readings less than 70 mg/dl (3.9 mmol/L) WITH symptoms?

- Never 1-3 times 1 time/week 2-3 times/week 4-5 times/week Almost daily

52. How often, in the last month, have you had readings less than 70 mg/dl (3.9 mmol/L) WITHOUT symptoms?

- Never 1-3 times 1 time/week 2-3 times/week 4-5 times/week Almost daily

53. How low does your blood sugar go before you feel symptoms?

- Above 70 mg/dL 60 – 69 mg/dL 50 – 59 mg/dL 40 – 49 mg/dL less than 40mg/dL

54. To what extent can you tell by your symptoms that your blood sugar is low?

- Never Rarely Sometimes Often Always

Diabetes Management:

55. Are you under the care of an endocrinologist or diabetes specialist? YES NO

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

If no, who helps you look after your diabetes? _____

56. What is your last HbA1C result? _____ Date: _____

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

58. How do you administer your insulin? Insulin injection Insulin Pump

59. If you use insulin injections, please answer the following questions:

67.a. How many injections do you administer per day? _____

67.b. What is the average total insulin that you take per day? _____

60. If you use an insulin pump, please answer the following questions:

a. What is the average total BASAL INSULIN that you require per day? _____

b. What is the average total BOLUS insulin that you use per day? _____

61. Please Circle *all* the insulin preparations that you are currently using?

Rapid acting:	Short acting	Intermediate acting:	Long acting:	Mixed insulin:	Other: (write in if not listed)
Humalog/Lispro	Regular	NPH	Lantus/ Glargine	50/50	
Novolog/Aspart	Humulin R	Humulin N	Levemir/ Detemir	70/30	
Apidra/Glulisine	Novolin R	Novolin N		75/25	Non-Insulin
Exubera/ inhaled insulin					Symlin/ Pramlintide

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

62. Medical History Please list any relevant medical problems not listed in the previous sections of the form.				
Major Illness	Date Onset	Current Status **	Date Resolved	Treatment (medication/surgery etc)

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

63. Surgical History (Please print clearly)			
Surgery	Date	Outcome	Complications

Additional Medical/ Surgical Background

64. Do you have a history of liver disease? YES NO

65. Have you had any type of cancer including skin cancer? YES NO

66. If yes to the previous question, please explain:

67. Have you ever had a transplant other than kidney? YES NO

68. If yes to the previous question, what organ(s)?

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

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

70. List known allergies to medications: _____

71. Referral Information (please print clearly)
How did you find out about this program?
<input type="checkbox"/> Doctor <input type="checkbox"/> Newspaper <input type="checkbox"/> Friend <input type="checkbox"/> DRIwebsite <input type="checkbox"/> Other patient <input type="checkbox"/> Magazine <input type="checkbox"/> Other_____

If you were referred to us by a doctor, complete the information below.

72. Referring Physician (please print clearly)			
Name (Last, MI, First include MD, PhD etc.)			
<input type="checkbox"/> Family practitioner <input type="checkbox"/> Internist <input type="checkbox"/> Endocrinologist/Diabetologist			
Address			
City	State/Province	Zip/Postal Code	E-Mail Address (if known)
Work Telephone (if outside the US, include country code)		Fax Number	

During the next 28 days of monitoring, complete one section of the diary below for each **hypoglycemic event** that meets the following criteria:

- a. Any fingerstick glucose reading equal to or less than **54mg/dl (3.0mmol/L)**
- b. Any symptoms of hypoglycemia even without a fingerstick reading

Answer **all** questions in the box and do not leave any blanks. Write N/A if not applicable.

If you do not have any episodes of hypoglycemia during the 28 days check this box.

Date: _____ Time: _____ Blood sugar Value: _____ OR Low				
1. Symptoms felt or what did you notice? (Please circle <u>all</u> the symptoms you had)				
Sweating	Problems with Vision	Seizure	OR	None
Shaking	Change in behaviour	Other _____		
Heart palpitations	Confusion	_____		
2. The reaction was recognized by (Please circle <u>one</u>):				
Yourself	Routine test on your meter	Someone else		
3. Treatment for the reaction needed (Please circle <u>all</u> that apply):				
Juice/Food	Help from someone else	Injection of glucagon		Hospital/Ambulance

Date: _____ Time: _____ Blood sugar Value: _____ OR Low				
1. Symptoms felt or what did you notice? (Please circle <u>all</u> the symptoms you had)				
Sweating	Problems with Vision	Seizure	OR	None
Shaking	Change in behaviour	Other _____		
Heart palpitations	Confusion	_____		
2. The reaction was recognized by (Please circle <u>one</u>):				
Yourself	Routine test on your meter	Someone else		
3. Treatment for the reaction needed (Please circle <u>all</u> that apply):				
Juice/Food	Help from someone else	Injection of glucagon		Hospital/Ambulance

Date: _____ Time: _____ Blood sugar Value: _____ OR Low				
1. Symptoms felt or what did you notice? (Please circle <u>all</u> the symptoms you had)				
Sweating	Problems with Vision	Seizure	OR	None
Shaking	Change in behaviour	Other _____		
Heart palpitations	Confusion	_____		
2. The reaction was recognized by (Please circle <u>one</u>):				
Yourself	Routine test on your meter	Someone else		
3. Treatment for the reaction needed (Please circle <u>all</u> that apply):				

5/2014

During the next 28 days of monitoring, complete one section of the diary below for each **hypoglycemic event** that meets the following criteria:

- c. Any fingerstick glucose reading equal to or less than **54mg/dl (3.0mmol/L)**
- d. Any symptoms of hypoglycemia even without a fingerstick reading

Answer **all** questions in the box and do not leave any blanks. Write N/A if not applicable.

If you do not have any episodes of hypoglycemia during the 28 days check this box.

Date: _____		Time: _____		Blood sugar Value: _____		OR		Low	
1. Symptoms felt or what did you notice? (Please circle <u>all</u> the symptoms you had)									
Sweating		Problems with Vision		Seizure		OR		None	
Shaking		Change in behaviour		Other _____					
Heart palpitations		Confusion		_____					
2. The reaction was recognized by (Please circle <u>one</u>):									
Yourself		Routine test on your meter			Someone else				
3. Treatment for the reaction needed (Please circle <u>all</u> that apply):									
Juice/Food		Help from someone else		Injection of glucagon		Hospital/Ambulance			

Date: _____		Time: _____		Blood sugar Value: _____		OR		Low	
1. Symptoms felt or what did you notice? (Please circle <u>all</u> the symptoms you had)									
Sweating		Problems with Vision		Seizure		OR		None	
Shaking		Change in behaviour		Other _____					
Heart palpitations		Confusion		_____					
2. The reaction was recognized by (Please circle <u>one</u>):									
Yourself		Routine test on your meter			Someone else				
3. Treatment for the reaction needed (Please circle <u>all</u> that apply):									
Juice/Food		Help from someone else		Injection of glucagon		Hospital/Ambulance			

Date: _____		Time: _____		Blood sugar Value: _____		OR		Low	
1. Symptoms felt or what did you notice? (Please circle <u>all</u> the symptoms you had)									
Sweating		Problems with Vision		Seizure		OR		None	
Shaking		Change in behaviour		Other _____					
Heart palpitations		Confusion		_____					
2. The reaction was recognized by (Please circle <u>one</u>):									
Yourself		Routine test on your meter			Someone else				
3. Treatment for the reaction needed (Please circle <u>all</u> that apply):									
Juice/Food		Help from someone else		Injection of glucagon		Hospital/Ambulance			

Body Mass Index (BMI) Conversion Table

Height ↓ Inches	Weight →																					
	45.3 kg	49.9 lb	54.4 lb	59.0 lb	63.5 lb	68.0 lb	72.6 lb	77.1 lb	81.7 lb	86.2 lb	90.7 lb	95.3 lb	99.8 lb	104.3 lb	108.9 lb	113.4 lb	117.9 lb	122.5 lb	127.0 lb	131.5 lb	136.1 lb	
55	23.24	25.56	27.89	30.21	32.54	34.86	37.19	39.51	41.84													
56	22.43	24.67	26.92	29.16	31.40	33.65	35.89	38.13	40.37	42.62												
57	21.64	23.80	25.96	28.13	30.29	32.46	34.62	36.79	38.95	41.12	43.28											
58	20.90	22.99	25.08	27.17	29.26	31.35	33.44	35.53	37.62	39.71	41.80	43.89										
59	20.20	22.22	24.24	26.26	28.28	30.29	32.32	34.33	36.35	38.37	40.39	42.41	44.43									
60	19.53	21.48	23.43	25.39	27.34	29.29	31.25	33.20	35.15	37.11	39.06	41.01	42.96	44.92	46.87	48.82	50.78	52.73	54.68	56.64	58.59	
61	18.89	20.78	22.67	24.56	26.45	28.34	30.23	32.12	34.01	35.90	37.79	39.68	41.57	43.46	45.35	47.24	49.13	51.02	52.90	54.79	56.68	
62	18.29	20.12	21.95	23.78	25.61	27.44	29.26	31.09	32.92	34.75	36.58	38.41	40.24	42.07	43.90	45.72	47.55	49.38	51.21	53.04	54.87	
63	17.71	19.48	21.26	23.03	24.80	26.57	28.34	30.11	31.88	33.66	35.43	37.20	38.97	40.74	42.51	44.28	46.06	47.83	49.60	51.37	53.14	
64	17.16	18.88	20.60	22.31	24.03	25.75	27.46	29.18	30.90	32.61	34.33	36.05	37.76	39.48	41.20	42.91	44.63	46.34	48.06	49.78	51.49	
65	16.64	18.30	19.97	21.63	23.30	24.96	26.62	28.29	29.95	31.62	33.28	34.94	36.61	38.27	39.94	41.60	43.26	44.93	46.59	48.26	49.92	
66	16.14	17.75	19.37	20.98	22.60	24.21	25.82	27.44	29.05	30.67	32.28	33.89	35.51	37.12	38.74	40.35	41.96	43.58	45.19	46.81	48.42	
67	15.66	17.23	18.79	20.36	21.93	23.49	25.06	26.62	28.19	29.76	31.32	32.89	34.46	36.02	37.59	39.15	40.72	42.29	43.85	45.42	46.99	
68	15.20	16.72	18.24	19.77	21.29	22.81	24.33	25.85	27.37	28.89	30.41	31.93	33.45	34.97	36.49	38.01	39.53	41.05	42.57	44.09	45.61	
69	14.77	16.24	17.72	19.20	20.67	22.15	23.63	25.10	26.58	28.06	29.53	31.01	32.49	33.96	35.44	36.92	38.39	39.87	41.35	42.82	44.30	
70	14.35	15.78	17.22	18.65	20.09	21.52	22.96	24.39	25.83	27.26	28.70	30.13	31.57	33.00	34.44	35.87	37.30	38.74	40.17	41.61	43.04	
71	13.94	15.34	16.74	18.13	19.52	20.92	22.32	23.71	25.10	26.50	27.89	29.29	30.68	32.08	33.47	34.87	36.26	37.66	39.05	40.45	41.84	
72	13.54	14.92	16.27	17.63	18.99	20.34	21.70	23.05	24.41	25.77	27.12	28.48	29.84	31.19	32.55	33.90	35.26	36.62	37.97	39.33	40.69	
73	13.14	14.51	15.83	17.15	18.47	19.79	21.11	22.43	23.75	25.07	26.39	27.71	29.02	30.34	31.66	32.98	34.30	35.62	36.94	38.26	39.58	
74	12.74	14.12	15.41	16.69	17.97	19.26	20.54	21.83	23.11	24.39	25.68	26.96	28.25	29.53	30.81	32.10	33.38	34.66	35.95	37.23	38.52	
75	12.34	13.71	14.99	16.25	17.50	18.75	20.00	21.25	22.50	23.75	25.00	26.25	27.49	28.75	30.00	31.25	32.50	33.75	35.00	36.25	37.50	
76	11.94	13.31	14.61	15.82	17.04	18.26	19.47	20.69	21.91	23.13	24.34	25.56	26.78	27.99	29.21	30.43	31.65	32.86	34.08	35.30	36.52	

From Bray, G.A., et al.: Evaluation of the obese subject. 1. An algorithm. JAMA, 235: 1487, 1976

**PROOF OF MEDICAL CARE BY YOUR PRIMARY PHYSICIAN
Of GREATER THAN 6 MONTHS**

Date: _____/_____/_____

Name of Patient: _____

Name of Primary Care Physician: _____

Address: _____

Tel: _____

This letter is to confirm that I have been providing care to this patient for more than 6 months and continues to be under my medical care.

I support this patient's application for islet transplant clinical trials.

Sincerely,

Signature of Primary Care Physician

_____/_____/_____
Date signed

**PROOF OF MEDICAL CARE BY YOUR DIABETES CARE SPECIALIST
(ENDOCRINOLOGIST OR DIABETOLOGIST) GREATER THAN 6 MONTHS**

Date: _____/_____/_____

Name of Patient: _____

Name of Diabetes Care Specialist:

Address: _____

Tel: _____

This letter is to confirm that I have been providing care to this patient for more than 6 months.

This patient has the following diabetes related problems:

- hypoglycemia unawareness
- severe hypoglycemia
- labile diabetes
- diabetes complications
 - retinopathy
 - nephropathy
 - neuropathy
 - gastroparesis
- cardiovascular disease
 - If yes, please specify _____
- none of the above

I support this patient's application for islet transplant clinical trials

Sincerely,

Signature of Diabetes Care Specialist

_____/_____/_____
Date signed