BLOOD SUGAR RECORD AND HYPOGLYCEMIC EVENTS

CIT CORE

Subject ID ___ ___ - ___ ___- ___ ___ ___

Instructions for completing this eCRF: In A1, enter the date of the blood sugar/insulin record you wish to enter. Then, in A2, enter the total insulin dose the subject administered on this date. In A3, enter the blood sugar readings taken on this date. After each blood sugar reading, click SAVE.

When you have entered all of the blood sugar readings associated with a date, click START NEW DATE. The database will provide the next calendar date in A1. You will then start at A1 again, and enter the date for the next set of blood sugar and insulin records. If there are no blood sugar records on a date, click START NEW DATE again to go to the next date. You will be prompted to confirm that there were no records for the date you wish to skip.

All data entered will populate two tables (one for blood sugar and one for insulin), below.

A. BLOOD SUGAR AND INSULIN RECORDS

1. Date: __ __/__ __ __/__ __ __ __ (A.1.Date) BLDInsDT
   (dd/mmm/yyyy)
   ☐ No Insulin or Blood Sugar Readings for this date (A.1.a) InsulinBSReadingsNA
2. Enter total insulin administered on this date: ☐ units ☐ not available (A.2) InsulinNA
   (A.2) Insulin

(Skip Q 1 & 2 after first blood sugar entry until START NEW DATE is clicked on**)**

3. Enter each blood sugar reading recorded for this date:

Blood sugar reading: _____ 1○ mg/dl 2○ mmol/L (A.3.b.BSR) BLDSugarRdg (A.3.b.Unit) BLDSugarRdgUnit

OR 1○ Low 2○ High *(if glucometer does not register a numerical value for a 'Low' or 'High' reading)*

If Blood sugar reading not available: 3○ Blood sugar reading not available (A.3.a.i) BLDSugarRdgLow

Time: ☐☐ ☐☐ (A.3.a.Hour, Min) BLDSugarTimeHour, BLDSugarTimeMin

*00-24 hrs. 00-59 mins.**
**prefill mins. with 00*

4. If applicable, select 'Meal Code': 1○ 1 = pre-meal 2○ 2 = 2 hours post-meal 3○ 3 = bedtime (A.4) MealCode

ADD NEW ENTRY

START NEW DATE

If a Blood sugar reading is under 54 mg/dl, Low, or Blood sugar reading not available, please complete Part B, next page. If not, skip part B.

B. HYPOGLYCEMIC EVENTS

This section will be triggered for each blood sugar reading < 54 mg/dL, Low, or Blood sugar reading not available. Each of these entries will have an associated Hypoglycemic Event record available. All entries will be visible on a growing table. An 'Add Hypo Event' button will also be available below this table to enter any additional events.

1. Hypoglycemia symptoms (select all that apply):

   a. ☐ Autonomic (B.1.a) HypoAuto

   b. ☐ Visual (B.1.b) HypoVisu

   c. ☐ Behavioral (B.1.c) HypoBeha

   d. ☐ Other neuro (B.1.d) HypoOther

   e. ☐ Confusion (B.1.e) HypoConf

   f. ☐ Seizures (B.1.f) HypoSeiz

   g. ☐ No symptoms [if chosen, all other options should be greyed out] (B.1.g) HypoNone

   h. ☐ No symptoms recorded or recalled [if chosen, all other options should be greyed out] (B.1.h) HypoNoRecorded

2. The reaction was recognized by...(please indicate one) (B.2) reaction

   1○ Yourself

   2○ Routine test on meter

   3○ Someone else

   4○ Unknown

3. Treatment for the reaction needed...(please check all that apply)

   a. ☐ Help from someone else (B.3.a) TrtHelp

   b. ☐ Juice/food/glucose tablets (B.3.b) TrtJuice

   c. ☐ Injection of glucagon (B.3.c) TrtInject

   d. ☐ Hospital/ambulance (B.3.d) TrtHosp

   e. ☐ Unknown (B.3.e) TrtUnk

   f. ☐ None (B.3.f) TrtNone

C. COMMENTS (C) comment

Subject ID ____ ____ -____ ____ - ____ ____ ____

A. Blood Type

1. Date of blood typing: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (A.1) VisitDT *(dd/mmm/yyyy)* (A.1.ND) VisitDTND ☐ Not Done

2. Blood type: ○ A ○ B ○ AB ○ O (A.2) BLType
   1 2 3 4

B. HLA typing

1. Date of HLA typing : __ __/__ __ __/__ __ __ __ (B.1) HLADT *(dd/mmm/yyyy)* (B.1.ND) HLADTND ☐ Not Done

HLA Antigen	Test Method (Select one)	Results (Choose from pick lists: at least one of i or ii must be filled in for a-c)
a. HLA-A (B.1.a) HLA_A	1 O Molecular 2 O Serologic	i.___ HLA-A (1st allele) (B.1.a.i) HLA_A1 ii.___ HLA-A (2nd allele) (B.1.a.ii) HLA_A2
b. HLA-B (B.1.b) HLA_B	1 O Molecular 2 O Serologic	i.___ HLA-B (1st allele) (B.1.b.i) HLA_B1 ii.___ HLA-B (2nd allele) (B.1.b.ii) HLA_B2
c. HLA-DR (B.1.c) HLA_DR	1 O Molecular 2 O Serologic	i.___ HLA-DR (1st allele) (B.1.c.i) HLA_DR1 ii.___ HLA-DR (2nd allele) (B.1.c.ii) HLA_DR2

C. COMMENTS (optional) (C) Comments

Subject ID ____ ____ -____ ____ - ____ ____ ____ Page 1 of 1

A. Continuous Glucose Monitoring System (CGMS)

No Yes

1. 0○ 1○ Was CGMS data collected for this subject for this visit? (A.1) NotDone

   a. Reason (A.1.a) Reason

If No is selected in Item 1, 1a must be completed and items 1b-1d are not required.

If Yes is selected in Item 1, 1a must not be completed and items 1b-1d are required.

b. Monitoring start date and time : (A.1.b) StartDT	__ __ / __ __ __ / __ __ __ __ *(dd/mmm/yyyy)*	__ __ __ __ *(0000-2359)*
c. Monitoring stop date and time: (A.1.c) StopDT	__ __ / __ __ __ / __ __ __ __ *(dd/mmm/yyyy)*	__ __ __ __ *(0000-2359)*
d. Date file sent to DCC: (A.1.d) FileSentDate	__ __ / __ __ __ / __ __ __ __ *(dd/mmm/yyyy)*	__ __ __ __ *(0000-2359)*

Subject ID ____ ____ -____ ____ - ____ ____ ____

A. LYMPHOCYTOTOXIC CROSS-MATCH

1. Recipient Serum Date: __ __ / __ __ __ / __ __ __ __ *(dd/mmm/yyyy)*(A.1)(SerumDate)
(A.2)(CrossmatchDate)
2. Date Crossmatch Performed: __ __ / __ __ __ / __ __ __ __ (*dd/mmm/yyyy*) ⬭ (*click to copy date)*

If recipient serum date is the same as the date crossmatch performed, go to Q4.

. If date of crossmatch is within 30 days of recipient serum date, go to Q3.

If date of crossmatch is not within 30 days of recipient serum date,
fresh recipient serum must be obtained for crossmatch.
Enter new recipient serum date in Question 1.

No Yes (A.3)(Pregnancy)
3. (0) ⬭ (1) ⬭ Has the subject experienced a pregnancy, infection, or received blood products since the date recipient serum was obtained?

Fresh recipient serum must be obtained for crossmatch. Obtain fresh serum and enter correct dates in Q1 & Q2.
Continue to Question 4.

Subject ID ____ ____ -____ ____ - ____ ____ ____

(A.4)(Source)

4. Donor Cell Source: (1)○ (PBMC) or (2) ○ (Spleen/lymph node)

	Cross-match	Results (Select one)	Method (Select one)
a.	Donor T Cell	(1) ○ Negative (2) ○ Positive (A.4.a)(DTResults) (A.4.a)(DTResults	(1) ○ NIH CDC (A.4.a)(DTMethod) (2) ○ NIH ext CDC (A.4.a)(DTMethod) (3) ○ Amos CDC (A.4.a)(DTMethod) (4) ○ AHG CDC (A.4.a)DTMethod() (5) ○ ELISA (A.4.a)(DTMethod) (6) ○ Flow Cytometry (A.4.a)(DTMethod)
b.	Donor B Cell	(1) ○ Negative (2) ○ Positive (A.4.b)(DBResults) (A.4.b)(DBResults)	(1) ○ NIH CDC (A.4.b)(DBMethod) (2) ○ NIH ext CDC (A.4.b)(DBMethod) (3) ○ Amos CDC (A.4.b)(DBMethod) (4) ○ AHG CDC (A.4.b)(DBMethod) (5) ○ ELISA (A.4.b)(DBMethod) (6) ○ Flow Cytometry (A.4.b)(DBMethod)
c.	Auto T Cell	(1) ○ Negative (2) ○ Positive (3) ○ Not Done (A.4.c)(ATResults) (A.4.c)(ATResults) (A.4.c)(ATResults)	(1) ○ NIH CDC (A.4.c)(ATMethod) (2) ○ NIH ext CDC (A.4.c)(ATMethod)) (3) ○ Amos CDC (A.4.c)(ATMethod)) (4) ○ AHG CDC (A.4.c)(ATMethod)) (5) ○ ELISA (A.4.c)(ATMethod)) (6) ○ Flow Cytometry (A.4.c)(ATMethod))
d.	Auto B Cell	() ○ Negative () ○ Positive () ○ Not Done (A.4.d)(ABResults) (A.4.d)(ABResults) (A.4.d)(ABResults)	() ○ NIH CDC (A.4.d)(ABMehod) () ○ NIH ext CDC (A.4.d)(ABMehod) () ○ Amos CDC (A.4.d)(ABMehod) () ○ AHG CDC (A.4.d)(ABMehod) () ○ ELISA (A.4.d)(ABMehod) () ○ Flow Cytometry (A.4.d)(ABMehod)

B. COMMENTS (optional) (B)(Comment)

F. GFR

No (0) Yes (1) (F.1) GFREstimationPerformed

1. ○ ○ Was the GFR calculation using CKD-EPI performed?

a. Date of serum creatinine draw: (F.1.a) GFRSerumCreatinineDrawDT ___ ___ / ___ ___ ___ / ___ ___ ___ ___ *(dd/mmm/yyyy)*

b. Serum creatinine [ ] (F.1.b) GFRSerumCreatinineValue (F.1.b.Unit) UnitGFRSerumCreatinine ○ (mg/dL) (1) or ○ (µmol/L) (2)

c. Age [ ] years (F.1.c) GFRAge

(F.1.d) GFRRace d. Race ○ African American (1) ○ All other races (2) ○ Not Reported (3)

(F.1.e) GFRGender e. Gender ○ Male (1) ○ Female (2)

(F.1.e) GFRValue f. GFR Value [background calculation] mL/min/1.73 m²

g. Reason: [(F.1.e) GFRReason]

Subject ID ____ ____ -____ ____ - ____ ____ ____

A. INFORMED CONSENT (each consent signed will add to a growing table)

1. Type of consent (select one): (1)(ConsentType)

(1) ○ Screening

(2) ○ Transplant

2. a. Version number of consent document: ☐ N/A(2.a.1)(VersionNumNA)
(2.a)(VersionNum)

b. Version date: __ __ / __ __ __ / __ __ __ __ ☐ N/A(2.b.1)(VersionDTNA)
(2.b)(VersionDT) *(dd/mmm/yyyy)*

3. Date informed consent signed: __ __ / __ __ __ / __ __ __ __ **ADD NEW ENTRY**
(3)(InfConsDT) *(dd/mmm/yyyy)*

YES NO

4. (1)○ (0)○ Does the consent contain long-term storage questions?
(4)(Longterm)

YES NO

a. (1) ○ (0) ○ The subject agreed to permit the collection and storage of blood samples for future research studies.
(4.a)(ResearchStudy)

YES NO

b. (1) ○ (0) ○ The subject agreed to permit the collection and storage of blood samples for future genetic testing.
(4.b)(GeneticTesting)

Subject ID ____ ____ -____ ____ - ____ ____ ____

A. PRA (METHOD MUST BE FLOW)

(A.1) PRADT

1. Date of test ___ ___ / ___ ___ ___ / ___ ___ ___ ___ *(dd/mmm/yyyy)*

(A.1) TestND ☐ *Not done*

2. Class I Antibody Screen (A.2) PRAIResults

Results (select one) (If Negative or Not Performed, skip Q2.a)

○ Positive ○ Negative ○ Not Performed

a. Class I Specificity Screen

Results: (A.2.a.i) PRAIPercent

i. PRA % ☐

Method: (Flow/Luminex)

ii. ☐ Specificity (A.2.a.ii) PRAISpecificity

iii. ☐ Single Antigen (A.2.a.iii) PRAIAntigen

iv. Specificities Defined (A.2.a.iv) PRAIDefined

☐1 ☐2 ☐3 ☐4 ☐5 ☐6

☐7 ☐8 ☐9 ☐10 ☐11 ☐12

3. Class II Antibody Screen

Results (select one) (If Negative or Not Performed, skip Q3.a)

○ Positive ○ Negative ○ Not Performed (A.3) PRAIIResults

a. Class II Specificity Screen

Results: (A.3.a.i) PRAIIPercent

i. PRA % ☐

Method: (Flow/Luminex)

ii. ☐ Specificity (A.3.a.ii) PRAIISpecificity

iii. ☐ Single Antigen (A.3.a.iii) PRAIIAntigen

iv. Specificities Defined (A.3.a.iv) PRAIIDefined

☐1 ☐2 ☐3 ☐4 ☐5 ☐6

☐7 ☐8 ☐9 ☐10 ☐11 ☐12

MEDICAL AND DIABETES HISTORY

Subject ID ____ ____ -____ ____ - ____ ____ ____

A. DIABETES HISTORY

1. Year diagnosed with diabetes: _____ (A.1) DiagYr
   (yyyy)
2. Year insulin therapy began: _____ (A.2) TherapyYr
   (yyyy)

B. DIABETES KETOACIDOSIS (DKA):

1. Has the subject experienced DKA within the last 12 months? (select one) (B.1) ExpDKA
   - ○ Yes 1
   - ○ No 2
   - ○ Unknown 3

2. Has the subject been hospitalized for DKA within the last 12 months? (select one) (B.2) HospDKA
   - ○ Yes 1
     - a. Specify number of hospitalizations in the last 12 months _____ (B.2.a) HospDKASP
   - ○ No 2
   - ○ Unknown 3

C. MEDICAL HISTORY

	Assessment	Any significant medical history?		If Yes, please give details.
		No	**Yes**	
1.	Skin	○ 0	○ 1	(C.1) Skin
2.	Head, Eyes, Ears, Nose, Throat	○ 0	○ 1	(C.2) Head
3.	Respiratory	○ 0	○ 1	(C.3) Resp
4.	Cardiovascular	○ 0	○ 1	(C.4) Card
5.	Gastrointestinal	○ 0	○ 1	(C.5) Gast
6.	Endocrine/Metabolic (except Diabetes)	○ 0	○ 1	(C.6) Endo
7.	Genitourinary/Reproductive	○ 0	○ 1	(C.7) Geni
8.	Neurological	○ 0	○ 1	(C.8) Neur
9.	Blood/Lymphatic	○ 0	○ 1	(C.9) Blood
10.	Musculoskeletal	○ 0	○ 1	(C.10) Muscu
11.	Hepatic/Biliary	○ 0	○ 1	(C.11) Hepatic
12.	Allergies/Immunologic	○ 0	○ 1	(C.12) Allerg
13.	Psychological/Psychiatric	○ 0	○ 1	(C.13) Psych
14.	Other		☐	(C.14) Other

D. COMMENTS (optional) (D.1) Comments

Subject ID ____ ____ -____ ____ - ____ ____ ____

A. PREGNANCY TEST

No Yes

1.0○ 1○ Was a pregnancy test performed? (A.1) PregnancyPerformed

a. Date of test : ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (A.1.a) TestDT

(dd/mmm/yyyy)

b. Type of test (A.1.b) Type

1○ Serum

2○ Urine

c. Results (A.1.c) Results

1○ Negative

2○ Positive

d. If no, confirm reason:

☐ Subject is male. (A.1.d) Reason

If Question 1c is 'positive' pre-transplant, exclude the subject from the study.

CaptionPositiveResults

If Question 1c is 'positive' post-transplant, follow protocol specific guidelines.

2. COMMENTS (optional) (A.2) Comment

Subject ID ____ ____ -____ ____ - ____ ____ ____

A. CRITERIA FOR PREMATURE DISCONTINUATION OF STUDY TREATMENT

If one or more of these five criteria are answered YES, begin **Reduced Follow-Up Schedule.**

	No	Yes	
1.	○	○	The subject is unwilling or unable to comply with the protocol. (A.1) IsUnwilling
2.	○	○	The investigator believes that the study treatment is no longer in the best interest of the subject. (A.2) NoLongerBest
3.	○	○	The renal allograft is lost and the subject elects to terminate chronic immunosuppression. (A.3) IsLostTerminate
4.	○	○	Graft Failure: absence of insulin production by transplanted islets, as evidenced by c-peptide < 0.3 ng/mL. This is determined by (1) c-peptide <0.3 ng.mL on random testing, followed by (2) c-peptide <0.3 ng/mL at baseline, and at 60 and 90 minutes after MMTT. C-peptide levels obtained in the course of the MMTT will be run at the core lab in Seattle, WA. (A.4) IsGraftFailure
5.	○	○	An unexpected, related serious adverse event. (A.5) IsSeriousAdverse

B. COMMENTS (optional)

(B) Comments

A. INCLUSION CRITERIA

Subjects must meet all of the following criteria to be considered eligible for participation in the study.

	No	Yes	
1.	○ 0	○ 1	Male and female subjects 18 to 68 years of age. (A.1) Age
2.	○ 0	○ 1	Subjects who are able to provide written informed consent and to comply with the procedures of the study protocol. (A.2) Consent
3.	○ 0	○ 1	Subjects in the United States must have one of the following payment mechanisms in place: (A.3) Payment a) ☐ Medicare, (A.3.a) Medicare b) ☐ A third-party insurer who agrees, via pre-authorization, to pay for participation in the study, or (A.3.b) ThirdParty c) ☐ Another mechanism of payment (self-pay, hospital, university, donations, etc.) for participation in the study. (A.3.c) OtherPay
4.	○ 0	○ 1	Clinical history compatible with Type 1 diabetes (T1D) with disease onset < 40 years of age and insulin dependent for ≥ 5 years at the time of enrollment, and a sum of subject age and insulin dependent diabetes duration of ≥ 28. (A.4) Type1
5.	○ 0	○ 1	Absent stimulated c-peptide (<0.3 ng/mL) in response to a mixed meal tolerance test (Boost® 6mL/kg body weight to a maximum of 360 mL; another product with equivalent caloric and nutrient content may be substituted for Boost®) measured at 60 and 90 min after the start of consumption. (A.5) CPeptide
6.	○ 0	○ 1	Post-renal transplant ≥ 3 months and taking appropriate calcineurin inhibitor based maintenance immunosuppression ([tacrolimus alone or in conjunction with sirolimus, mycophenolate mofetil, myfortic, or azathioprine; or cyclosporine in conjunction with sirolimus, mycophenolate mofetil, or myfortic] ± Prednisone ≤ 10 mg/day). (A.6) PostRenalTransplant
7.	○ 0	○ 1	Stable renal function as defined by creatinine of no more than one third greater than the average creatinine determination performed in the 3 previous months prior to islet transplantation, until rejection, obstruction, or infection is ruled out. (A.7) StableRenalFunction

A. INCLUSION CRITERIA (*continued*)

	No	Yes
	0	1
8.	○	○

Subjects who meet one of the options are eligible for transplantation:

(A.8) SubEligibleTransplant

a. ☐ Reduced awareness of hypoglycemia manifested by a Clarke score of 4 or more measured upon study enrollment and at least one episode of severe hypoglycemia in the 12 months prior to study enrollment. This criterion requires that there has been involvement in intensive diabetes management. Such management must be under the direction of an endocrinologist, diabetologist, or diabetes specialist with at least 3 clinical evaluations during the 12 months prior to study enrollment.

(A.8.a) ClarkeScore

b. ☐ After enrollment followed by at least 4 months of IIT, a subject must have a reduced awareness of hypoglycemia manifested by a Clarke score of 4 or more and at least 1 episode of severe hypoglycemia.

(A.8.b) Month4IIT

c. ☐ Any subject not meeting the hypoglycemia option must receive intensive insulin therapy (IIT) for a minimum of 12 months under the care of an experienced diabetes specialist. At the end of this period s/he must have both an HbA1c greater than or equal to 7.5% and a value for HbA1c within the 95% confidence interval for the HbA1c in the preceding month of IIT. If the HbA1c has fallen below this 95% confidence interval, the patient must be followed for at least one more month of IIT to achieve a stable HbA1c above 7.5%, as per the above definition.

(A.8.c) Month12IIT

d. ☐ Any subject not meeting one of the above options in this criterion may continue IIT beyond the required 12 months. The subject will be eligible for islet transplantation if the second or third option is met after 12 months of IIT.

(A.8.d) SubEligibleTransplant

B. EXCLUSION CRITERIA

Subjects who meet any of the following criteria are not eligible for participation in the study.

	No	Yes		
			(B.1) BMI	
1.	○ 0	○ 1	Weight more than 90 kg or body mass index >30 kg/m^2.	
			(B.2) Insulin	
2.	○ 0	○ 1	Insulin requirement of > 1.0 IU/ kg/day or <15 U / day.	
			(B.3) OtherTransplants	
3.	○ 0	○ 1	Other (non-kidney) organ transplants except prior failed pancreatic graft, where graft failure is attributed to thrombosis within the first 4 weeks or to other technical reasons that require graft pancreatectomy; with the graft pancreatectomy occurring more than 6 months prior to enrollment.	
			(B.4) Retinopathy	
4.	○ 0	○ 1	Untreated or unstable proliferative diabetic retinopathy.	
			(B.5) BP	
5.	○ 0	○ 1	Blood Pressure: SBP > 160 mmHg or DBP > 100 mmHg despite treatment with antihypertensive agents.	
			(B.6) GFR	
6.	○ 0	○ 1	Calculated glomerular filtration rate (GFR) of < 40 mL/min/1.73m^2 using the subject's measured serum creatinine and the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation. Strict vegetarians (vegans) will be excluded only if their estimated GFR is ≤ 35 mL/min/1.73m^2.	
			(B.7) Albuminuira	
7.	○ 0	○ 1	Proteinuria (albumin/creatinine ratio or ACr >300 mg/g) of new onset since kidney transplantation.	
			(B.8) AntiHLA	
8.	○ 0	○ 1	Calculated panel-reactive anti-HLA antibodies >50%. Subjects with calculated panel reactive anti-HLA antibodies ≤ 50% will be excluded if any of the following are detected:	
			a) ☐ Positive crossmatch,	(B.8.a) Crossmath
			b) ☐ Islet donor-directed anti-HLA antibodies detected by Luminex Single/Antigen specificity bead assay including weakly reactive antibodies that would not be detected by a flow cross-match, or	(B.8.b) IsletDonor
			c) ☐ Antibodies to the renal donor (i.e. presumed denovo).	(B.8.c) AntiBodies
9.	○ 0	○ 1	**<u>For female subjects:</u>** Positive pregnancy test, presently breastfeeding, or unwillingness to use effective contraceptive measures for the duration of the study and 4 months after discontinuation.	
			(B.9) PregTest	
			<u>For male subjects</u>: Intent to procreate during the duration of the study or within 4 months after discontinuation or unwillingness to use effective measures of contraception.	
			Oral contraceptives, Norplant®, Depo-Provera®, and barrier devices with spermicide are acceptable contraceptive methods; condoms used alone are not acceptable.	

B. EXCLUSION CRITERIA *(continued)*

	No	Yes	
			(B.10) Infection
10.	○ 0	○ 1	Presence or history of active infection including hepatitis B, hepatitis C, HIV or tuberculosis (TB). Subjects with laboratory evidence of active infection are excluded even in the absence of clinical evidence of active infection.
			(B.11) EBV
11.	○ 0	○ 1	Negative screen for Epstein-Barr Virus (EBV) by IgG determination at the time of screening or previous kidney transplant.
			(B.12) aspergilus
12.	○ 0	○ 1	Invasive aspergillus, histoplasmosis, and coccidoidomycosis, infection within one year prior to study enrollment.
			(B.13) malignancy
13.	○ 0	○ 1	Any history of malignancy except for completely resected squamous or basal cell carcinoma of the skin.
			(B.14) AlcAbuse
14.	○ 0	○ 1	Known active alcohol or substance abuse.
			(B.15) FactorV
15.	○ 0	○ 1	Evidence of Factor V Leiden mutation.
			(B.16) Coagulophay
16.	○ 0	○ 1	Any coagulopathy or medical condition requiring long-term anticoagulant therapy (e.g., warfarin) after islet transplantation (low-dose aspirin treatment [325 mg PO]is allowed) or patients with an INR >1.5. The use of Plavix is allowed only in conjunction with mini-laparotomy procedure at the time of the islet transplant.
			(B.17) Cardiac
17.	○ 0	○ 1	Severe co-existing cardiac disease, characterized by any one of these conditions: a) ☐ Recent myocardial infarction (within past 6 months); (B.17.a) Infarction b) ☐ Evidence of ischemia on functional cardiac exam within the last year;(B.17.b) Ischemia c) ☐ Left ventricular ejection fraction <30%; or (B.17.c) Ejection d) ☐ Valvular disease requiring replacement with prosthetic valve. (B.17.d) ValvularDisease
			(B.18) Liver
18.	○ 0	○ 1	Persistent elevation of liver function tests at the time of study entry. Persistent SGOT (AST), SGPT (ALT), alkaline phosphatase, or total bilirubin with values > 1.5 times normal upper limits will exclude a subject.
			(B.19) ActiveInfections
19.	○ 0	○ 1	Active infections (except mild skin and nail fungal infections).
			(B.20) pancreatits
20.	○ 0	○ 1	Acute or chronic pancreatitis.
			(B.21) peptic
21.	○ 0	○ 1	Active peptic ulcer disease, symptomatic gallstones, or portal hypertension.
			(B.22) AntiDiabetic
22.	○ 0	○ 1	Treatment with any anti-diabetic medication other than insulin within 4 weeks of enrollment.

B. EXCLUSION CRITERIA *(continued)*

	No	Yes	
			(B.23) OtherAgents
23.	○ 0	○ 1	Use of any investigational agents within 4 weeks of enrollment.
			(B.24) Vaccine
24.	○ 0	○ 1	Administration of live attenuated vaccine(s) within 2 months of enrollment.
			(B.25) MedCondition
25.	○ 0	○ 1	Any medical condition that, in the opinion of the investigator, will interfere with the safe participation of the trial. (Cancer screenings should be performed per current American Cancer Society guidelines).
			(B.26) ESRD
26.	○ 0	○ 1	Any condition other than T1D as the primary cause of end stage renal disease (ESRD) in the native kidney.
			(B.27) PCR
27.	○ 0	○ 1	Positive screen for BK virus by polymerase chain reaction (PCR) performed at the time of screening.
			(B.28) PreciousIslet
28.	○ 0	○ 1	A previous islet transplant.
			(B.29) PatientWithHBA1c
29.	○ 0	○ 1	A kidney transplant patient with type 1 diabetes who has an HbA1c < 7.5 and no history of severe hypoglycemia.

A. INCLUSION CRITERIA

Subjects must meet all of the following criteria to be considered eligible for transplantation.

	No	Yes	
			(A.1) Age
1.	○ 0	○ 1	Male and female subjects 18 to 68 years of age.
			(A.2) Consent
2.	○ 0	○ 1	Subjects who are able to provide written informed consent and to comply with the procedures of the study protocol.
			(A.3) Payment
3.	○ 0	○ 1	Subjects in the United States must have one of the following payment mechanisms in place:

a) ☐ Medicare, (A.3.a) Medicare

b) ☐ A third-party insurer who agrees, via pre-authorization, to pay for participation in the study, or (A.3.b) ThidParty

c) ☐ Another mechanism of payment (self-pay, hospital, university, donations, etc.) for participation in the study. (A.3.c) OtherPay

			(A.4) Type1
4.	○ 0	○ 1	Clinical history compatible with Type 1 diabetes (T1D) with disease onset < 40 years of age and insulin dependent for ≥ 5 years at the time of enrollment, and a sum of subject age and insulin dependent diabetes duration of ≥ 28.
			(A.5) Cpeptide
5.	○ 0	○ 1	Absent stimulated c-peptide (<0.3 ng/mL) in response to a mixed meal tolerance test (Boost® 6mL/kg body weight to a maximum of 360 mL; another product with equivalent caloric and nutrient content may be substituted for Boost®) measured at 60 and 90 min after the start of consumption.
			(A.6) PostRenalTransplant
6.	○ 0	○ 1	Post-renal transplant ≥ 3 months and taking appropriate calcineurin inhibitor based maintenance immunosuppression ([tacrolimus alone or in conjunction with sirolimus, mycophenolate mofetil, myfortic, or azathioprine; or cyclosporine in conjunction with sirolimus, mycophenolate mofetil, or myfortic] ± Prednisone ≤ 10 mg/day).
			(A.7) StableRenalFunction
7.	○ 0	○ 1	Stable renal function as defined by creatinine of no more than one third greater than the average creatinine determination performed in the 3 previous months prior to islet transplantation, until rejection, obstruction, or infection is ruled out.

A. INCLUSION CRITERIA (*continued*)

	No	Yes	
			(A.8) Age
8.	○ 0	○ 1	Subjects who meet one of the options are eligible for transplantation:

(A.8.a) ClarkeScore

a. ☐ Reduced awareness of hypoglycemia manifested by a Clarke score of 4 or more measured upon study enrollment and at least one episode of severe hypoglycemia in the 12 months prior to study enrollment. This criterion requires that there has been involvement in intensive diabetes management. Such management must be under the direction of an endocrinologist, diabetologist, or diabetes specialist with at least 3 clinical evaluations during the 12 months prior to study enrollment.

(A.8.b) Month4IIT

b. ☐ After enrollment followed by at least 4 months of IIT, a subject must have a reduced awareness of hypoglycemia manifested by a Clarke score of 4 or more and at least 1 episode of severe hypoglycemia.

(A.8.c) Month12IIT

c. ☐ Any subject not meeting the hypoglycemia option must receive intensive insulin therapy (IIT) for a minimum of 12 months under the care of an experienced diabetes specialist. At the end of this period s/he must have both an HbA1c greater than or equal to 7.5% and a value for HbA1c within the 95% confidence interval for the HbA1c in the preceding month of IIT. If the HbA1c has fallen below this 95% confidence interval, the patient must be followed for at least one more month of IIT to achieve a stable HbA1c above 7.5%, as per the above definition.

(A.8.d) AfterMonth12IIT

d. ☐ Any subject not meeting one of the above options in this criterion may continue IIT beyond the required 12 months. The subject will be eligible for islet transplantation if the second or third option is met after 12 months of IIT.

B. EXCLUSION CRITERIA

Subjects who meet any of the following criteria are not eligible for transplantation.

	No	Yes	
			(B.1) BMI
1.	○ 0	○ 1	Weight more than 90 kg or body mass index >30 kg/m^2.
			(B.2) Insulin
2.	○ 0	○ 1	Insulin requirement of > 1.0 IU / kg/day or <15 U / day.
			(B.3) OtherTransplants
3.	○ 0	○ 1	Other (non-kidney) organ transplants except prior failed pancreatic graft, where graft failure is attributed to thrombosis within the first 4 weeks or to other technical reasons that require graft pancreatectomy; with the graft pancreatectomy occurring more than 6 months prior to enrollment.
			(B.4) Retinophathy
4.	○ 0	○ 1	Untreated or unstable proliferative diabetic retinopathy.
			(B.5) BP
5.	○ 0	○ 1	Blood Pressure: SBP > 160 mmHg or DBP > 100 mmHg despite treatment with antihypertensive agents.
			(B.6) Glomerular
6.	○ 0	○ 1	Calculated glomerular filtration rate (GFR) of < 40 mL/min/1.73m^2 using the subject's measured serum creatinine and the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation. Strict vegetarians (vegans) will be excluded only if their estimated GFR is ≤ 35 mL/min/1.73m^2.
			(B.7) Proteinuria
7.	○ 0	○ 1	Proteinuria (albumin/creatinine ratio or ACr >300 mg/g) of new onset since kidney transplantation.
			(B.8) AntiHLA
8.	○ 0	○ 1	Calculated panel-reactive anti-HLA antibodies >50%. Subjects with calculated panel reactive anti-HLA antibodies ≤ 50% will be excluded if any of the following are detected:

a) ☐ Positive crossmatch, (B.8.a) CrossMatch

b) ☐ Islet donor-directed anti-HLA antibodies detected by Luminex Single/Antigen specificity bead assay including weakly reactive antibodies that would not be detected by a flow cross-match, or (B.8.b) IsletDonor

c) ☐ Antibodies to the renal donor (i.e. presumed denovo). (B.8.c) Antibodies

9.	○ 0	○ 1	**<u>For female subjects:</u>** Positive pregnancy test, presently breastfeeding, or unwillingness to use effective contraceptive measures for the duration of the study and 4 months after discontinuation. (B.9) Pregnancy(B.) A

<u>For male subjects</u>: Intent to procreate during the duration of the study or within 4 months after discontinuation or unwillingness to use effective measures of contraception.

Oral contraceptives, Norplant®, Depo-Provera®, and barrier devices with spermicide are acceptable contraceptive methods; condoms used alone are not acceptable.

B. EXCLUSION CRITERIA *(continued)*

	No	Yes	
10.	○ 0	○ 1	(B.10) Infection Presence or history of active infection including hepatitis B, hepatitis C, HIV or tuberculosis (TB). Subjects with laboratory evidence of active infection are excluded even in the absence of clinical evidence of active infection.
11.	○ 0	○ 1	(B.11) EBV Negative screen for Epstein-Barr Virus (EBV) by IgG determination at the time of screening or previous kidney transplant.
12.	○ 0	○ 1	(B.12) Aspergillus Invasive aspergillus, histoplasmosis, and coccidoidomycosis, infection within one year prior to study enrollment.
13.	○ 0	○ 1	(B.13) Malignancy Any history of malignancy except for completely resected squamous or basal cell carcinoma of the skin.
14.	○ 0	○ 1	(B.14) AlcAbuse Known active alcohol or substance abuse.
15.	○ 0	○ 1	(B.15) FactorV Evidence of Factor V Leiden mutation.
16.	○ 0	○ 1	(B.16) Coagulopathy Any coagulopathy or medical condition requiring long-term anticoagulant therapy (e.g., warfarin) after islet transplantation (low-dose aspirin treatment [325 mg PO]is allowed) or patients with an INR >1.5. The use of Plavix is allowed only in conjunction with mini-laparotomy procedure at the time of the islet transplant.
17.	○ 0	○ 1	(B.17) Cardiac Severe co-existing cardiac disease, characterized by any one of these conditions: a) ☐ Recent myocardial infarction (within past 6 months); (B.17.a) Myocardial b) ☐ Evidence of ischemia on functional cardiac exam within the last year; (B.17.b) Ischemia c) ☐ Left ventricular ejection fraction <30%; or (B.17.c) ValvularDisease d) ☐ Valvular disease requiring replacement with prosthetic valve. (B.17.d) Ventricular
18.	○ 0	○ 1	(B.18) LiverFunction Persistent elevation of liver function tests at the time of study entry. Persistent SGOT (AST), SGPT (ALT), alkaline phosphatase, or total bilirubin with values > 1.5 times normal upper limits will exclude a subject.
19.	○ 0	○ 1	(B.19) Infections Active infections (except mild skin and nail fungal infections).
20.	○ 0	○ 1	(B.20) Pancreatitis Acute or chronic pancreatitis.
21.	○ 0	○ 1	(B.21) Peptic(B.) A Active peptic ulcer disease, symptomatic gallstones, or portal hypertension.

B. EXCLUSION CRITERIA *(continued)*

(B.23) OtherAgents

23. ○ 0 ○ 1 Use of any investigational agents within 4 weeks of enrollment.

(B.24) LiveVaccine

24. ○ 0 ○ 1 Administration of live attenuated vaccine(s) within 2 months of enrollment.

(B.25) MedCondition

25. ○ 0 ○ 1 Any medical condition that, in the opinion of the investigator, will interfere with the safe participation of the trial. (Cancer screenings should be performed per current American Cancer Society guidelines).

(B.26) ESRD

26. ○ 0 ○ 1 Any condition other than T1D as the primary cause of end stage renal disease (ESRD) in the native kidney.

(B.27) PCR

27. ○ 0 ○ 1 Positive screen for BK virus by polymerase chain reaction (PCR) performed at the time of screening.

28. ○ 0 ○ 1 A previous islet transplant. (B.28) previousIslet

29. ○ 0 ○ 1 A kidney transplant patient with type 1 diabetes who has an HbA1c < 7.5 and no history of severe hypoglycemia.

(B.29) hypoglycemia

Subject ID ____ ____ -____ ____ - ____ ____ ____

Report Number _____

A. ADVERSE EVENT

1. Date of adverse event _____
(dd/mmm/yyyy)
2. Date site became aware of AE _____
(dd/mmm/yyyy)
3. Adverse Event Term
4. Describe event or problem. (Include any details relating to diagnosis.)

No Yes

5. ○ ○ Is this an exacerbation of a pre-existing condition (existing prior to enrollment)?
6. Describe relevant tests/laboratory data, including dates.
7. Describe other relevant history, including preexisting medical conditions. (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Subject ID ____ ____ -____ ____ - ____ ____ ____

Report Number _____

8. Outcomes attributed to adverse event (Check all that apply)
(ALL choices below represent an SAE except "None of the above")

☐ Death: ___ ___/___ ___ ___/___ ___ ___ ___
(dd/mmm/yyyy)

☐ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Disability
☐ Congenital anomaly
☐ Required intervention to prevent permanent impairment/damage
☐ Important medical event as determined by the site PI or designee
☐ None of the above (non-serious AE)

If outcome changes to an SAE during a postcomplete change, Q8a and 8b pop-up.

8a. Date the Adverse Event became a Serious Adverse Event:
__ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

8b. Date the site became aware that the Adverse Event became a Serious Adverse Event:
__ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

9. Intensity - Please follow the guidelines in the "TCAE in Trials of Adult Pancreatic Islet Transplantation"
(Select one)
○ Mild/Grade I
○ Moderate/Grade II
○ Severe/Grade III
○ Life-threatening/Grade IV
○ Death/Grade V
(If question 9 is Death/Grade V, then go to question 10)

10. Was/will an autopsy be performed? **(Select one)**
○ No
○ Yes ——— Please provide a de-identified copy to the DCC
○ Unknown

11. Indicate outcome of the event
○ Continuing
○ Resolved (or resolved with sequelae)-If resolved, give date of resolution __ __/__ __ __/__ __ __ __
(dd/mmm/yyyy)

Subject ID ____ ____ -____ ____ - ____ ____ ____

Report Number _____

No **Yes**

12. ○ ○ Was a study-related islet transplant procedure ever initiated for this subject?
    - a. Relationship to islet transplantation
      - ○ Definite
      - ○ Probable
      - ○ Possible
      - ○ Unlikely
      - ○ Unrelated, Explain: _____
    - b. Action taken regarding islet transplantation
      - ○ Infusion not started
      - ○ None
      - ○ Interrupted but completed
      - ○ Prematurely terminated

No **Yes**

13. ○ ○ Has the subject ever received immunosuppression and/or infection prophylaxis?
    - a. Relationship to immunosuppression/infection prophylaxis
      - ○ Definite
      - ○ Probable
      - ○ Possible
      - ○ Unlikely
      - ○ Unrelated, Explain: _____
    - b. Action taken regarding immunosuppression/infection prophylaxis
      - ○ None
      - ○ Dose reduced
      - ○ Interrupted
      - ○ Discontinued
      - ○ Dose increased

No **Yes**

14. ○ ○ Was the subject ever receiving intensive insulin therapy (IIT) at the time of the adverse event?
    - a. Relationship to intensive insulin therapy
      - ○ Definite
      - ○ Probable
      - ○ Possible
      - ○ Unlikely
      - ○ Unrelated, Explain: _____
    - b. Action taken regarding intensive insulin therapy
      - ○ None
      - ○ Dose reduced
      - ○ Interrupted
      - ○ Discontinued
      - ○ Dose increased

B. SUSPECT MEDICATION(S)

	Suspect Medication 1	Suspect Medication 2	Suspect Medication 3
1. Name	i. Islet Transplantation ☐ Purified Human Pancreatic Islets (check if ever recieved islets) ☐ Transplant Procedure (check if ever had transplant procedure initiated)	ii. Immunosuppression and infection prophylaxis	iii. Intensive Insulin Therapy
2. Dose	i.		ii. Units/day
3. Therapy dates (if unknown, give best estimate)	i. Date of most recent islettransplantation __ __ / __ __ __ / __ __ __ __ *(dd/mmm/yyyy)*		ii. Introduction Date _ _ / _ _ _ / _ _ _ _ iii. Date of last dose _ _ / _ _ _ / _ _ _ _ *(dd/mmm/yyyy)*
4. Diagnosis for use	Type I Diabetes Mellitus	Immunosuppression	Type I Diabetes Mellitus
5. Event abated after use stopped or dose reduced?	i. ○ No ○ Yes ○ Doesn't apply	ii. ○ No ○ Yes ○ Doesn't apply	
6.Event reappeared after reintroduction?	i. ○ No ○ Yes ○ Doesn't apply	ii. ○ No ○ Yes ○ Doesn't apply	
7. Lot number	i.		
8. Expiration Date	N/A		

Subject ID ____ ____ -____ ____ - ____ ____ ____

Report Number _____

C. OTHER MEDICATIONS

What concomitant medications was the subject receiving at the time of the event?
(Exclude treatment of event)

INSTRUCTIONS:

1. Select the buttons below to add data to the Other Medications text box.

   ○ Select to add data that has been entered into the subject's Concomitant Meds eCRF

   ○ Select to add data that has been entered into the subject's Study Treatment Regimen eCRF

2. Please review added data carefully for accuracy and modify this form and the Concomitant Meds eCRF and/or the Study Treatment Regimen eCRF as needed.

3. If the subject was on **insulin therapy at the time of the event**, their insulin therapy must be **added to the text box below**.

4. Add any additional medication information, if applicable.

Subject ID ____ ____ -____ ____ - ____ ____ ____

A. CLINICAL ASSESSMENT

1. Date of Assessment ___ ___ /___ ___ ___ /___ ___ ___ ___ *(dd/mmm/yyyy)* (A.1) AssessmentDT
2. Temperature ____ (°C) (A.2) Temperature
3. Pulse ____ (beats/min) (A.3) Pulse
4. Blood Pressure
   a. ___ ___ ___ / ___ ___ ___ (mm Hg) ☐ Not obtained
   (A.4.a.i) BP1a (A.4.a.ii) BP2a (A.4.a) BPaNO
   b. ___ ___ ___ / ___ ___ ___ (mm Hg) ☐ Not obtained
   (A.4.b.i) BP1b (A.4.b.ii) BP2b (A.4.b) BPbNO
5. Mean Arterial Pressure ___ ___ ___ / ___ ___ ___ (mm Hg) [This will be autocalculated on the web.](A.5) MAP
6. Weight ____ (kg) (A.6) Weight
7. Height ____ (cm) (A.7) Height
8. BMI ____ (kg/m²) [This will be autocalculated on the web.] (A.8) BMI

B. INITIAL PHYSICAL EXAMINATION
(skip part B after initial physical examination)

Assessment	Not Performed	Normal	Abnormal	If abnormality, please describe	
(B.1) 1. Skin Skin	1○	2○	3○		(B.1.a) SkinSP
(B.2) 2. Head, eyes, ears, nose, throat Head	1○	2○	3○		(B.2.a) HeadSP
(B.3) 3. Respiratory Resp	1○	2○	3○		(B.3.a) RespSP
(B.4) 4. Cardiovascular Cardio	1○	2○	3○		(B.4.a) CardioSP
(B.5) 5. Abdominal Abdom	1○	2○	3○		(B.5.a) AbdomSP
(B.6) 6. Genitourinary/ reproductive Genit	1○	2○	3○		(B.6.a) GenitSP
(B.7) 7. Neurological Neuro	1○	2○	3○		(B.7.a) NeuroSP
(B.8) 8. Lymph nodes Lymph	1○	2○	3○		(B.8.a) LymphSP
(B.9) 9. Musculoskeletal Muscu	1○	2○	3○		(B.9.a) MuscuSP
(B.10) 10. Psychological/ psychiatric Phych	1○	2○	3○		(B.10.a) PhychSP
(B.11) 11. Other (specify) Other ____ (B.11.a) OtherSpecify	1○	2○	3○		(B.11.b) OtherSP

C. FOLLOW-UP PHYSICAL EXAMINATION

Assessment	Not Performed	Normal	Abnormal but unchanged since last visit	New abnormality	If new abnormality, please describe
(C.1) 1. Skin Skin2	1	2	3	4	((C.1.a) SkinSP2
(C.2) 2. Head, eyes, ears, nose, throat Head2	1	2	3	4	(C.2.a)HeadSP2
(C.3) 3. Respiratory Resp2	1	2	3	4	(C.3.a)RespSP2
(C.4) 4. Cardiovascular Cardio2	1	2	3	4	(C.4.a) CardioSP2
(C.5) 5. Abdominal Abdom2	1	2	3	4	(C.5.a)AbdomSP2
(C.6) 6. Genitourinary/ reproductive Genit2	1	2	3	4	(C.6.a)GenitSP2
(C.7) 7. Neurological Neuro2	1	2	3	4	(C.7.a)NeuroSP2
(C.8) 8. Lymph nodes Lymph2	1	2	3	4	(C.8.a)LymphSP2
(C.9) 9. Musculoskeletal Muscu2	1	2	3	4	(C.9.a)MuscuSP2
(C.10) 10. Psychological/ psychiatric Phych2	1	2	3	4	(C.10.a)PhychSP2
(C.11) 11. Other (specify) Other2	1	2	3	4	(C.11.b)OtherSP2

(C.11.a)OtherSpecify2

D. COMMENTS (optional) (D) comments

Subject ID ____ ____ -____ ____ - ____ ____ ____

A. RENAL DONOR HISTORY

1. Renal donor: 1◯Living 2◯ Deceased (A.1) Donor

2. Renal donor CMV status: 1◯ Positive 2◯ Negative 3◯ Unknown (A.2) DonorCMV

3. Renal donor HLA type:

HLA Antigen	Results (Choose from pick lists: at least one of i or ii must be filled in for a-c)
a. HLA-A	i.___ HLA-A (1st allele) (A.3.a.i) HLA_A1 ii.___ HLA-A (2nd allele) (A.3.a.ii) HLA_A2
b. HLA-B	i.___ HLA-B (1st allele) (A.3.b.i) HLA_B1 ii.___ HLA-B (2nd allele) (A.3.b.ii) HLA_B2
c. HLA-DR	i.___ HLA-DR (1st allele) (A.3.c.i) HLA_DR1 ii.___ HLA-DR (2nd allele) (A.3.c.ii) HLA_DR2

B. RENAL RECIPIENT HISTORY

No Yes

1. 0◯ 1◯ Was the subject treated by dialysis prior to renal transplant? (B.1) Dialysis

   a. Start date of dialysis treatment: __ __/__ __ __/__ __ __ __ (B.1.a) DialysisStartDT
   (dd/mmm/yyy)

2. Date of renal transplant: __ __/__ __ __/__ __ __ __ (B.2) TransplantDT
   (dd/mmm/yyy)

3. Epstein-Barr Virus IgG antibody (EBV IgG) status at most recent renal transplant: (B.3)EBVIgG
   1◯ Positive
   2◯ Negative
   3◯ Unknown

B. RENAL RECIPIENT HISTORY (Continued)

No **Yes**

4. 0○ 1○ Has the recipient previously been treated with induction therapy?(B.4)PreTreated

- ☐ Anti-thymocyte globulin (horse or rabbit)(B.4)PreGlobulin
- ☐ OKT3(B.4)PreOKT3
- ☐ Daclizumab(B.4) PreDaclizumab
- ☐ Alemtuzumab(B.4) PreAlemtuzumab
- ☐ Basiliximab(B.4) PreBasiliximab
- ☐ Other(B.4) PreOther (B.4) PreOtherSP

Please specify: ____

No **Yes**

5. 0○ 1○ Has the recipient previously experienced episodes of renal rejection since their kidney transplant?(B.5) RenalRejection

a. Date: __ __/__ __ __/__ __ __ __ **ADD NEW ENTRY**
(dd/mmm/yyyy)
(5.a) RenalRejectionDT

b. What was the treatment?

- ☐ Anti-thymocyte globulin (horse or rabbit) (5.b) AntiGlobulin
- ☐ OKT3 (5.b) OKT3
- ☐ Alemtuzumab (5.b) Alemtuzumab
- ☐ Rituximab (5.b) Rituximab
- ☐ IVIG (5.b) IVIG
- ☐ Steroids (5.b) Steroids
- ☐ Change in chronic therapy (5.b) ChangeTherapy
- ☐ Other (5.b) Other

Please specify: ____
(5.b) OtherSP

Subject ID ____ ____ -____ ____ - ____ ____ ____

A. RETINOPATHY (A) Text1

No Yes

1. 0○ 1○ Was eye exam performed? (A.1) EyeExam

a. Date of last eye exam: __ __/__ __ __/__ __ __ __ (A.1.a) EyeExamDT
(dd/mmm/yyyy)

CorrectedOSODNR

b. Corrected visual acuity: **OS** **OD** ☐ **Not Reported**

20/ ☐ ☐
(A.1.b.OS)CorrectedOS (A.1.b.OD)CorrectedOD

c. Legally blind:

	Yes	No	Not Reported	
i. Left eye	1○	0○	2○	(A..1.c.i)BlindLeftEye
ii. Right eye	1○	0○	2○	(A.1.c.ii)BlindRightEye

d. What was the stage of diabetic retinopathy? (A.1.d.OS)

	OS	OD	(A.1.d.OD)
Not present StageRetOS	1○	1○	StageRetOD
Mild nonproliferative	2○	2○	
Moderate nonproliferative	3○	3○	
Severe nonproliferative	4○	4○	
Proliferative	5○	5○	
Not reported	6○	6○	

e. What was the stage of macular edema? (A.1.e.OS)

	OS	OD	(A.1.e.OD)
Not present MacularEdemaOS	1○	1○	MacularEdemaOD
Mild	2○	2○	
Moderate	3○	3○	
Severe	4○	4○	
Not reported	5○	5○	

f. Other ocular conditions:

	OS			OD			
	Present	Not present	Not Reported	Present	Not present	Not Reported	
(A.f.i.OS) i. Cataracts CataractsOS	1○	2○	3○	1○	2○	3○	(A.f.i.OD) CataractsOD
(A.f.ii.OS) ii. Vitreous hemorrhage HemorrhageOS	1○	2○	3○	1○	2○	3○	(A.f.ii.OD) HemorrhageOD
(A.f.iii.OS) iii. Retinal detachment DetachmentOS	1○	2○	3○	1○	2○	3○	(A.f.iii.OD) DetachmentOD
(A.f.iv.OS) iv. Glaucoma GlaucomaOS	1○	2○	3○	1○	2○	3○	(A.f.iv.OD) GlaucomaOD

g. Reason ☐ (A.g) Reason

Subject ID ____ ____ -____ ____ - ____ ____ ____

B. COMMENTS (optional) (B) Comments

Subject ID ____ ____ -____ ____ - ____ ____ ____

A. REQUIREMENTS FOR A SECOND TRANSPLANT

Questions 1-11 are mandatory.

	No	Yes	
1.	○ 0	○ 1	Subject received ≥5,000 IEq/kg with the first transplant, but failed to achieve or maintain insulin independence *[if No, Ineligible]*. (A.1) InsulinIndependence
2.	○ 0	○ 1	Subject has been compliant with study monitoring and prescribed immunosuppressivetherapy *[if No, Ineligible]*. (A.2) ComplaintMonitoring
3.	○ 0	○ 1	No evidence of a serious and life-threatening infection, adverse event, or other condition that precludes attempting an intraportal injection or continuation of thepost-transplant treatment regimen *[if No, Ineligible]*. (A.3) SeriousInfection
4.	○ 0	○ 1	Subject has no unresolved SAEs *[if No, Ineligible]*. (A.4) UnresolvedSAEs
5.	○ 0	○ 1	No evidence of post-transplant lymphoproliferative disorder (PTLD), requiring complete withdrawal from immunosuppressive therapy *[if No, Ineligible]*. (A.5) PTLD
6.	○ 0	○ 1	No evidence of hypersensitization, allergic responses, or other potentially serious drug reactions to medications required by the protocol *[if No, Ineligible]*. (A.6) NoHypersensitization
7.	○ 0	○ 1	Stable renal function as defined as being a creatinine of no more than one third greater than the average creatinine determination performed in the 3 previous months, until rejection, obstruction, or infection is ruled out *[if No, Ineligible]*. (A.7) StableRenalFunction
8.	○ 0	○ 1	Subject has no medical condition that, in the opinion of the investigator, will interfere with a safe and successful second islet transplant *[if No, Ineligible]*. (A.8) MedicalCondition
9.	○ 0	○ 1	It has been < 8 months since the first islet transplant *[if No, Ineligible]*. (A.9) Been8Months
10.	○ 0	○ 1	Absence of anti-HLA antibodies directed to the kidney transplant or to the current islet preparation detected by Luminex Single Antigen/specificity bead assay (including weakly reactive antibodies that would not be detected by a flow cross-match). All kidney and currently-proposed islet preparation donor specificities must be avoided in 2nd and 3rd islet transplants.*[if No, Ineligible]*. (A.10) AntiHLA
11.	○ 0	○ 1	Basal and stimulated C-peptide levels are both ≥ 0.3 ng/mL (0.1 nmol/L). *[If No, Item 10.a must be Yes, and there must be a date in 10.a.i to be eligible. Otherwise, Ineligible.]* (A.11) SCReview

	No	Yes	
a.	○ 0	○ 1	The Steering Committee has reviewed and given final approval for a second infusion.

i. Date of SC approval: __ __/ __ __ __ / __ __ __ __ *(dd/mmm/yyyy)* (A.12) SCApprovalDT

Subject ID ____ ____ -____ ____ - ____ ____ ____

B. COMMENTS (optional) (B) Commnet

This form must be entered on the CIT website within 24 hours of study termination.

1. Date of Study Termination: ___ ___/___ ___ ___ /___ ___ ___ ___ *(dd/mmm/yyyy)*
   (1) VisitDT
2. Date of last follow up visit: ___ ___/___ ___ ___ /___ ___ ___ ___ *(dd/mmm/yyyy)*
   (2) LateVisitDT
3. Indicate the primary reason the subject will no longer be followed: (select one)
   (3) Reason

- ◯ Subject completed study procedures per protocol 1
- ◯ Subject withdrew consent 2
- ◯ Lost to follow-up (Unable/unwilling to travel/moved from area/unable to locate) 3
- ◯ Successful Intensive Insulin Therapy prior to transplantation 4
- ◯ Subject death 5
  - Complete the Adverse Event form
- ◯ Screening Eligibility form completed, indicating a "screening success", but subject did not actually meet eligibility criteria 6
  - Select the eligibility criteria that caused the subject to become ineligible (check all that apply)
  - (add list box of eligibility criteria - include instructions for selecting multiple criteria)
  - Complete the Major Protocol Deviation form to explain
- ◯ Screening Eligibility form completed, indicating a "screening success", but subject became ineligible while on wait list 7
  - Select the eligibility criteria that caused the subject to become ineligible (check all that apply)
  - (add list box of eligibility criteria - include instructions for selecting multiple criteria)
- ◯ (8) Subject matched for transplant but did not actually meet transplant eligibility criteria
  - Do NOT complete this Study Termination eCRF if the subject received induction immunosuppression medications in preparation for a CIT-06 islet transplant.
  - Complete the Major Protocol Deviation form to explain
- 9 ◯ Other

Please specify: ☐

4. Comments (optional): (4) Comment

☐

A. INDUCTION MEDICATIONS

Drug	Date	Total Dose on this Date (mg)
1○ ATG (Drug)Drug		
2○ Daclizamab	(dd/mmm/yyyy)	(Dose) Dose
N/A○ Basiliximab	(EnterDT) EnterDT	
15○Other	(DrugOther) DrugOther	

ADD NEW ENTRY

B. IMMUNUSUPPRESSIVE/ANTI-INFLAMMATORY MEDICATIONS

Drug	Date	Total Dose on this Date (mg)
3○ Etanercept		
4○ Methylprednisolone	(dd/mmm/yyyy)	(Dose) Dose
(Drug)Drug	(EnterDT) EnterDT	

ADD NEW ENTRY

Sections A-B will be greyed out after induction is complete.

C. MAINTENANCE IMMUNOSUPPRESSIVE MEDICATIONS

ADD NEW ENTRY

Drug	**Total Dose (mg) / Day**	Start Date	Stop Date
5○ Tacrolimus			
N/A○ Cyclosporine	(Dose) Dose	(dd/mmm/yyyy)	(dd/mmm/yyyy)
6○ Sirolimus		(StartDT) StartDT	(StopDT)StopDT
16○ Other	(DrugOther) DrugOther		

└ If Other, please complete Major Protocol Deviation form.

D. TROUGH LEVELS

ADD NEW ENTRY

Drug	Date of Draw	Trough Level (ng/mL)
5○ Tacrolimus		(ToughLevel) ToughLevel
N/A○ Cyclosporine	(dd/mmm/yyyy)	☐ Undetectable
6○ Sirolimus	(EnterDT) EnterDT	
17○ Other	(DrugOther) DrugOther	

E. OTHER MAINTENANCE IMMUNOSUPPRESSION MEDICATIONS

ADD NEW ENTRY

Drug	**Total Dose (mg) / Day**	Start Date	Stop Date
7○ Mycophenolate mofetil			
18○ Mycophenolate sodium	(Dose) Dose	(dd/mmm/yyyy)	(dd/mmm/yyyy)
N/A○ Azathioprine		(StartDT) StartDT	(StopDT)StopDT
N/A○ None			

F. INFECTION PROPHYLAXIS MEDICATIONS

ADD NEW ENTRY

Drug	Total Dose / Day	Start Date	Stop Date
8○ TMP/SMX (SS=1 tab)*			
9○ Clotrimazole (troche)	(Dose) Dose	(dd/mmm/yyyy)	(dd/mmm/yyyy)
10○ Valganciclovir (mg)		(StartDT) StartDT	(StopDT)StopDT
N/A○ Unasyn (g)			

*single strength TMP = 80 mg; SMX = 400mg

G. ANTICOAGULANT MEDICATIONS

ADD NEW ENTRY

Drug	Total Dose (mg) / Day	Start Date	Stop Date
12○ Enoxaparin			
13○ Pentoxifylline	(Dose) Dose	(dd/mmm/yyyy)	(dd/mmm/yyyy)
14○ Aspirin		(StartDT) StartDT	(StopDT)StopDT

H. COMMENTS (optional)

Subject ID ____ ____ -____ ____ - ____ ____ ____

Date: ___ ___/___ ___ ___/___ ___ ___ ___ (N/A) SurveyDT
(dd/mmm/yyyy)

INSTRUCTIONS: Please ask the subject the appropriate question (A, B, **or** C) according to their current visit. **If their answer is "no" do not fill out the remainder of the survey. If their answer is "yes" proceed to question #1 and complete the survey.**

A. Screening Visit: "Have you experienced any hypoglycemia in the past 12 months?" 1◯Yes 0◯ No (N/A)
B. Wait List: "Have you experienced any hypoglycemia in the past 6 months?" 1◯Yes 0◯ No (N/A)
C. Post Transplant: "Have you experienced any hypoglycemia since your last visit?" 1◯Yes 0◯ No (N/A)
ExperHypo

1. Check the category that best describes you: (check only one) (1) Category
   1◯ I always have symptoms when my blood sugar is low
   2◯ I sometimes have symptoms when my blood sugar is low
   3◯ I no longer have symptoms when my blood sugar is low

2. Have you lost some of the symptoms that used to occur when your blood sugar was low? (2) Symptoms
   1◯ Yes
   0◯ No

3. In the past six months how often have you had hypoglycemia episodes where you felt confused, disoriented, or lethargic and were unable to treat yourself? (3) HypoConfused
   1◯ Never
   2◯ Once or twice
   3◯ Every other month
   4◯ Once a month
   5◯ More than once a month

Subject ID ____ ____ -____ ____ - ____ ____ ____

4. In the past twelve months, how often have you had hypoglycemia episodes where you were unconsious or had a seizure and needed glucagon or intravenous glucose? (4) HypoUnconsious

1 ◯ Never
2 ◯ 1 time
3 ◯ 2 times
4 ◯ 3 times
5 ◯ 4 times
6 ◯ 5 times
7 ◯ 6 times
8 ◯ 7 times
9 ◯ 8 times
10 ◯ 9 times
11 ◯ 10 times
12 ◯ 11 times
13 ◯ 12 times or more

5. How often in the last month have you had readings less than 70 mg/dl (3.9 mmol/L) with symptoms?(5) ReadingSymptoms

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

6. How often in the last month have you had readings less than 70 mg/dl (3.9 mmol/L) without symptoms? (6) ReadingWithoutSymptoms

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

7. How low does your blood sugar go before you feel symptoms? (7) LowBloodSugar

1 ◯ 60-69mg/dl (3.3-3.8 mmol/L)
2 ◯ 50-59mg/dl (2.8-3.2 mmol/L)
3 ◯ 40-49mg/dl (2.2-2.7 mmol/L)
4 ◯ < 40 mg/dl (2.2 mmol/L)

8. To what extent can you tell by your symptoms that your blood sugar is low? (8) ExtentLowBloodSugar

1 ◯ Never
2 ◯ Rarely
3 ◯ Sometimes
4 ◯ Often
5 ◯ Always

Subject ID ____ ____ -____ ____ - ____ ____ ____

Enter concomitant medications

A. Drug(DRUG)Drug	B.Start Date (STARTDT)StartDT	C.Stop Date (STOPDT) StopDT
	__ __ / __ __ __ / __ __ __ __ (dd/mmm/yyyy)	__ __ / __ __ __ / __ __ __ __ (dd/mmm/yyyy)

Save

Cancel

Delete

D. Comment: (COMMENTS) Comments

Enable Delete

(As drugs are saved, a table is created. Each entry can be edited)

Drug	Start Date	Stop Date	
			Edit

Subject ID ____ ____ -____ ____ - ____ ____ ____

A. FASTING AND POSTPRANDIAL C-PEPTIDE

☐ Not Done CPeptide1ND

1. a. Date of draw __ __ / __ __ __ / __ __ __ __ (A.1.a) DrawDT *(dd/mmm/yyyy)* Time of draw __ __ __ __ *(24-hour clock)* (A.1.a.time) DrawT

b. Fasting c-peptide ____ (A.1.b) CPept 1○ ng/mL 2○ nmol/L (A.1.b.Unit) CPeptUnt

0,1 ☐ undetectable (A.1.b) CPeptUnd

click to copy date ☐ Not Done CPeptide2ND

2. a. Date of draw __ __ / __ __ __ / __ __ __ __ (A.2.a) FirstPstDrawDT *(dd/mmm/yyyy)* Time of draw __ __ __ __ *(24-hour clock)* (A.2.time) FirstPstDrawT

b. First post-prandial c-peptide ____ (A.2.b) FirstPstCpep1○ ng/mL 2○ nmol/L (A.2.b.Unit) FirstPstCPeptUnt

0,1 ☐ undetectable (A.2.b) FirstPstPeptUnd

click to copy date ☐ Not Done CPeptide3ND

3. a. Date of draw __ __ / __ __ __ / __ __ __ __ (A.3.a) SecondPstDrawDT *(dd/mmm/yyyy)* Time of draw __ __ __ __ *(24-hour clock)* (A.3.a.time) SecondPstDrawT

b.Second post-prandial c-peptide ____ (A.3.b) SecondPstCPep1○ ng/mL 2○ nmol/L (A.3.b.Unit) SecondPstCPepUnt

0,1 ☐ undetectable (A.3.b) SecondPstCPepUnd

B. COMMENTS (B) Comments

Screening ID ____ ____ -____ ____ - ____ ____ ____

1. Date of birth ___ ___/___ ___ ___/___ ___ ___ ___ (1) DOB
   (dd/mmm/yyyy)

2. Gender (2) Gender
   1 ○ Male
   2 ○ Female

3. Ethnicity (Select one) (3) Ethnicity
   1 ○ Hispanic or Latino
   2 ○ Non-Hispanic or Non-Latino Origin
   3 ○ Unknown/not reported

4. Race (Check all that apply)
   - ☐ American Indian or Alaskan Native (4) Race1Al
   - ☐ Asian (4) Race2A
   - ☐ Black or African-American (4) RACE3AA
   - ☐ Native Hawaiian or other Pacific Islander (4) RACE6NH
   - ☐ White (4) RACE7W
   - ☐ Unknown/not reported (4) RACE8U

A. Date of Visit __ __/__ __ __/__ __ __ __ (A) VisitDT
(dd/mmm/yyyy)

B. QUESTIONS FOR FULL HYPO SCORE

1. How many hypoglycemic episodes in the past year have you needed help to recognize? ☐ (B.1)
recognize

2. How many hypoglycemic episodes in the past year have you needed help to treat? ☐ (B.2)
treat

3. How many hypoglycemic episodes in the past year have you treated with glucagon? ☐ (B.3)
glucagon

4. How many hypoglycemic episodes in the past year have required an ambulance call? ☐ (B.4)
ambulance

C. COMMENTS (C) Comments

1. Donor ID Number: _____ (1) DonorID

2. Islet lot number: ___ ___ -- _____ (2) IsletLot

3. Date of transplant: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (3) TransplantDT
(dd/mmm/yyyy)

4. Islet donor blood type: 1 ○ A 2 ○ B 3 ○ AB 4 ○ O (4) DonorBLType

5. Islet donor HLA type (5.a) DonorHLA_A (5.a.i) DonorHLA_A1 (5.a.ii) DonorHLA_A2
(5.b) DonorHLA_B (5.b.i) DonorHLA_B1 (5.b.ii) DonorHLA_B2
(5.c) DonorHLA_DR (5.c.i) DonorHLA_DR1 (5.c.ii) DonorHLA_DR2

HLA Antigen	Test Method (Select one)	Results (Choose from pick lists: at least one of i or ii must be filled in for a-c)
a. HLA-A	O Molecular O Serologic	i.___ HLA-A (1st allele) ii.___ HLA-A (2nd allele)
b. HLA-B	O Molecular O Serologic	i.___ HLA-B (1st allele) ii.___ HLA-B (2nd allele)
c. HLA-DR	O Molecular O Serologic	i.___ HLA-DR (1st allele) ii.___ HLA-DR (2nd allele)

6. Islet donor CMV status: 1 ○ Positive 2 ○ Negative (6) DonorCMV

7. Islet donor EBV status: 1 ○ Positive 2 ○ Negative (7) DonorEBV

8. Subject's weight on day -2 (prior to transplant): _____ kg (8) Weight

9. Time of initial skin puncture/first incision: __ __ __ __ (9) SkinPunctureT
(0000-2359)

10. Catheter introduction method: (select one) (10) CatheterMethod
1O Percutaneous transhepatic
2O Mini-laparotomy

(If Q.10 is answered mini-laparotomy, skip Q.11, Q.12 and Q.18)

11. Number of punctures through the liver capsule needed for placement: ☐ Not obtained
NumberPunctures (11) NumberPuncturesNO

12. Time of confirmed good position of the catheter: __ __ __ __ ☐ Not obtained
(0000-2359)
CatheterT (12) CatheterTNO

13. Time infusion started: __ __ __ __ (13) InfusionStartT
(0000-2359)

14. Time infusion ended: __ __ __ __ (14) InfusionEndT
(0000-2359)

15. Infusion method: (select one) (15) InfusionMethod
1O Gravity-fed bag set
2O Other, specify: _____ (15.other specify) InfusionMethodSP

16. Total volume infused (including rinse): _____ (mL) (16) TotalVolumeInfused

17. Total IEQ infused: _____ (17) TotalIEQ

18. Ablation method: (select one) (18) AblationMethod
- 1 ○ Gelfoam
- 2 ○ Collagen/thrombin paste
- 3 ○ Gel foam and collagen/thrombin paste
- 4 ○ Gel foam and coils
- 5 ○ Other, specify: [ ] (18.other specify) AblationMethodSP

19. Portal Pressure
- a. Portal pressure before infusion [ ] (mmHg) (19.a) PortalPresInf
- b. Peak portal pressure (during infusion) [ ] (mmHg) (19.b) PeakPortalPres
- c. Portal pressure after infusion [ ] (mmHg) (19.c) PortalPresAfterInf

20. Was the islet infusion... (20) IsletInfusion
- 1 ○ a. Completely infused without interruption
- 2 ○ b. Completely infused with interruption
- 3 ○ c. Not completely infused/prematurely terminated

If b or c, please explain/describe. If c, estimate fraction infused. (20.comment) IsletInfusionSP

[ ]

No Yes

21. 0 ○ 1 ○ Was IV heparin administered post-transplant per protocol? (21) IVHeparinAdmin

a. Reason: [ ]

(21.a) IVHeparinReason

No Yes

22. 0 ○ 1 ○ Was there evidence of an adverse event ***during infusion***? (22) AEDuringInf

Complete an Adverse Event form (22.a) CompleteAEText

23. Glucose finger stick
- a. 1 hour post-transplant [ ] 1 ○ mg/dL 2 ○ mmol/L

  OneHRPostTran (23.a) OneHRPostTranUnit (23.a unit)
- b. 2 hours post-transplant [ ] 1 ○ mg/dL 2 ○ mmol/L

  TwoHRPostTran (23.b) TwoHRPostTranUnit (23.b unit)

24. COMMENTS (optional) (24) Comment

[ ]

Date of Visit ___ ___ / ___ ___ ___ / ___ ___ ___ ___ VisitDT
(dd/mmm/yyyy)

A. COAGULATION STATUS

CoagulationDT

1. Date of draw ___ ___ / ___ ___ ___ / ___ ___ ___ ___ ☐ *Click to copy Date of Visit* (A.1)
(dd/mmm/yyyy) ☐ *Not done* (A) CoagulationND

2. PTT ☐ (seconds) (A.2) ☐ (Not obtained) (A.2.a)
PTT PTTNO

3. PT/INR ☐ (A.3) ☐ (Not obtained) (A.3.a)
PT PTNO

B. HEMATOLOGY

HematologyDT

1. Date of draw ___ ___ / ___ ___ ___ / ___ ___ ___ ___ ☐ *Click to copy Date of Visit* (B.1)
(dd/mmm/yyyy) ☐ *Not done (B.1)*
HematologyND

2. Hemoglobin ☐ 1○ (g/dL) or 2○ (g/L) ☐ (Not obtained) (B.2)
Hemoglobin (B.2) UnitHemoglobin (B.2.unit) HemogloginNO

3. Hematocrit ☐ 1○ (%) or 2○ (L/L) ☐ (Not obtained) (B.3)
Hematocrit (B.3) UnitHematocrit (B.3.unit) HematocritNO

4. White blood cell count ☐ ($x10^9$/L) ☐ (Not obtained) (B.4)
WBCount (B.4) WBCountNO

5. Neutrophils [total] ☐ 1○ ($x10^9$/L) or 2○ (/μL) ☐ (Not obtained) (B.5)
Neutrophils (B.5) UnitNeutrophils (B.5.unit) NeutrophilsNO

6. Lymphocytes [total] ☐ 1○ ($x10^9$/L) or 2○ (/μL) ☐ (Not obtained) (B.6)
Lymphocyte (B.6) UnitLymphocyte (B.6.unit) LymphocyteNO

7. Platelet count ☐ ($x10^9$/L) ☐ (Not obtained) (B.7)
Platelet (B.7) PlateletNO

C. SERUM CHEMISTRY

(C.1) SerumDT

1. Date of Draw ___ ___ / ___ ___ ___/ ___ ___ ___ ___ *(dd/mmm/yyyy)* ☐ *Click to copy Date of Visit* ☐ *Not done* (C.1) SerumND

2.	Sodium	☐ Sodium	1○ (mEq/L) or 2○ (mmol/L) (C.2.unit) UnitSodium	☐ Not obtained (C.2.) SodiumNO
3.	Potassium	☐ Potassium	1○ (mEq/L) or 2○ (mmol/L) (C.3.unit) UnitPotassium	☐ Not obtained (C.3) PotassiumNO
4.	Creatinine	☐ Creatinine	1○ (mg/dL) or 2○ (µmol/L) (C.4.unit) UnitCreatinine	☐ Not obtained (C.4) CreatinineNO
5.	Glucose	☐ Glucose	1○ (mg/dL) or 2○ (mmol/L) (C.5.unit) UnitGlucose	☐ Not obtained (C.5) GlucoseNO
6.	Albumin	☐ Albumin	1○ (g/dL) or 2○ (g/L) (C.6.unit) UnitAlbumin	☐ Not obtained (C.6) AlbuminNO
7.	Alk Phosphatase	☐ AlkPhos	(U/L)	☐ Not obtained (C.7) AlkPhosNO
8.	ALT (SGPT)	☐ ALT	1○ (µkat/L) or 2○ (U/L) (C.8.unit) UnitALT	☐ Not obtained (C.8) ALTNO
9.	AST (SGOT)	☐ AST	1○ (µkat/L) or 2○ (U/L) (C.9.unit) UnitAST	☐ Not obtained (C.9) ASTNO
10.	Magnesium	☐ Magnesium	1○ (mg/dL) or 2○ (mmol/L) or ○ (mEq/L) UnitMagnesium (10.unit)	☐ Not obtained (C.10) MagnesiumNO
11.	Total Bilirubin	☐ Birlirubin	1○ (mg/dL) or 2○ (mmol/L) (C.11.unit) UnitBirlirubin	☐ Not obtained (C.11) BirlirubinNO
12.	BUN	☐ BUN	1○ (mg/dL) or 2○ (mmol/L) (C.12.unit) UnitBUN	☐ Not obtained (C.12) BUNNO
13.	Calcium	☐ Calcium	1○ (mg/dL) or 2○ (mmol/L)(C.13.unit) UnitCalcium	☐ Not obtained (C.13) CalciumNO
14.	Chloride	☐ Chloride	1○ (mEq/L) or 2○ (mmol/L)(C.14.unit) UnitChloride	☐ Not obtained (C.14) ChlorideNO
15.	CO2	☐ CO2	1○ (mEq/L) or 2○ (mmol/L)(C.15.unit) UnitCO2	☐ Not obtained (C.15) CO2NO
16.	Gamma GT	☐ GammaGT	(IU/L)	☐ Not obtained (C.16) GammaGTNO
17.	Phosphorus	☐ Phosphorus	1○ (mg/dL) or 2○ (mmol/L)(C.17.unit) UnitPhosphorus	☐ Not obtained (C.17) PhosphorusNO

D. THYROID FUNCTION

(D.1) ThyroidDT

1. Date of Draw __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy) ☐ *Click to copy Date of Visit* ☐ *Not done* (D.1) ThyroidND

2. TSH ____ (mIU/L) (D.2) TSH ☐ Not obtained (D.2) TSHNO

E. FASTING LIPID PANEL

(E.1) FastingLipidDT

1. Date of Draw __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy) ☐ *Click to copy Date of Visit* ☐ *Not done* (E.1) FastingLipidND

(E.2) 2. Total Cholesterol ____ Cholesterol 1○ (mg/dL) or 2○ (mmol/L) UnitCholesterol ☐ Not obtained (E.2) CholesterolNO

(E.3) 3. LDL ____ LDL 1○ (mg/dL) or 2○ (mmol/L) UnitLDL ☐ Not obtained (E.3) LDLNO

(E.4) 4. HDL ____ HDL 1○ (mg/dL) or 2○ (mmol/L) UnitHDL ☐ Not obtained (E.4) HDLNO

(E.5) 5. Triglycerides ____ Triglycerides 1○ (mg/dL) or 2○ (mmol/L) TriglyceridesUnit ☐ Not obtained (E.5) TriglyceridesNO

F. GFR

No Yes (F.1) GFREstimationPerformed

1.0 ○ 1○ Does the subject have a history of allergies to seafood or iodine-containing products?

Use CKD-EPI to calculate GFR:

Notes: Serum creatinine result should come from central lab.
Items a-f must be completed for CIT-08 subjects.

GFREstimationPerformedND

a. Date of serum creatinine draw: __ __/ __ __ __/ __ __ __ (dd/mmm/yyyy) ☐ *Click to copy Date of Visit* ☐ *Not done*
(F.1.a) GFRSerumCreatinineDrawDT

b. Serum creatinine (F.1.b) GFRSerumCreatinineValue ____ 1○ (mg/dL) or 2○ (µmol/L) (F.1.b.unit) UnitGFRSerumCreatinine

c. Age ____ years (F.1.c) GFRAge

d. Race 1○ African American 2○ All other races (F.1.d) GFRRace

e. Gender 1○ Male 2○ Female (F.1.e) GFRGender

f. GFR Value background calculation mL/min/1.73 m^2 (F.1.f) GFRValue

Subject ID ____ ____ -____ ____ - ____ ____ ____

G. COMMENTS (optional) (G) Comment

This form must be entered on the CIT website within 24 hours of notification of a major protocol deviation. Major protocol deviations are deviations that impact the inclusion and/or exclusion criteria, consent violations, alteration of study therapy, or administration of prohibited medications.

1. Date of deviation: ___ ___ / ___ ___ ___ / ___ ___ ___ ___

(1) VisitDT *(dd/mmm/yyyy)*

2. Date site became aware of deviation: ___ ___/___ ___ ___/___ ___ ___ ___

(2) AwareDT *(dd/mmm/yyyy)*

3. Who identified the protocol deviation? (select one) (3) WhoID

1○ Principal Investigator 2○ Site Coordinator
3○ Monitor / Auditor 4○ NIH Medical Monitor
5○ NIH Project Manager 6○ DCC Protocol Coordinator

4. When did the protocol deviation occur? (select one) (4) WhenOccur

1○ Prior to study treatment
2○ After initiation of study treatment
3○ After discontinuation of study treatment, while on mandated protocol follow-up

5. Category of deviation: (select one) (5) Category

1○ Impacts the Inclusion and/or Exclusion criteria
2○ Involves consent violations
3○ Alters protocol-specified study therapy
4○ Impacts the ability to evaluate the endpoints of the study
5○ Involves administration of prohibited medications
6○ Other _____ (5.Other) CategoryTB

6. Provide a detailed description of the protocol deviation: (6) DeviationSP

7. Describe the corrective plan to ensure that this deviation does not occur again: (7) CorrectiveSP

8. Comments (optional) (8) Comment

Subject ID ___ ___ - ___ ___- ___ ___ ___

Minor protocol deviations are those that DO NOT impact the inclusion and/or exclusion criteria, consent violations, alteration of study therapy, or administration of prohibited medications.

1. Date of deviation: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (1) DeviationDT *(dd/mmm/yyyy)*

2. Provide a detailed description of the protocol deviation: (2) DeviationDesc

3. Comment (optional): (3) Comment

Subject ID ____ ____ -____ ____ - ____ ____ ____

A. REDUCED FOLLOW-UP

No (0) Yes (1)

1. ○ ○ Was follow-up visit (phone or in person) conducted? (A.1) (FollowUpVisit)

a. Date of contact or visit: __ __ / __ __ __ / __ __ __ __ (A.1.a)
(dd/mmm/yyyy) (FollowUpDT)

1) Which type of visit was conducted? (select one)(A.1.a.1)
(1) ○ Phone (FollowUpVisitType)
(2) ○ In person
(If Phone, skip section C; if In person, skip Section B)

b. Reason: _____ (A.1.b)
(FollowUpReason)

If Q.A1 is answered no, skip sections B and C.

B. PHONE FOLLOW-UP

No (0) Yes (1)

1. ○ ○ Has the subject experienced any Serious Adverse Events? (B.1) (SeriousAE)

a. **If yes, then complete the Adverse Event form.**

No (0) Yes (1)

2. ○ ○ Were QOL questionnaires mailed to the subject? (B.2) (QOLMail)

a. Date questionnaires mailed: __ __ / __ __ __ / __ __ __ __ (B.2.a)
(dd/mmm/yyyy) (QOLMailDT)

b. Reason: _____ (B.2.b)
(QOLMailReason)

	No	Yes	
3.	○ (0)	○ (1)	Has the subject experienced any hypoglycemic events grade 3-4 as defined in the Toxicity Criteria for Adverse Events? (HypglycemicE) (B.3.a)

a. **If yes, then complete the Adverse Event form.**

C. IN-PERSON FOLLOW-UP

	No	Yes	
1.	○ (0)	○ (1)	Has the subject experienced any Serious Adverse Events? (C.1)(InPersonFollowUpSAE)

a. **If yes, then complete the Adverse Event form.**

	No	Yes	
2.	○ (0)	○ (1)	Has the subject experienced any hypoglycemic events grade 3-4 as defined in the Toxicity Criteria for Adverse Events? (C.2) (ToxicCrieteriaAE)

a. **If yes, then complete the Adverse Event form.**

D. COMMENTS (optional) (D) (Comments)

Subject ID ____ ____ -____ ____ - ____ ____ ____

A. SEROLOGY

(DrawDate) DrawDT

Date sample drawn: _ _ /_ _ _ /_ _ _ _ (dd/mmm/yyyy)

Infectious Disease	Date Sample Drawn (dd/mmm/yyyy)	Negative (A.1) CmVlgG	Positive	Not Obtained
1. Cytomegalovirus IgG antibody (CMV IgG)	(A.1.Date) CmVlgGDT _ _ /_ _ _ /_ _ _ _ ○ click to copy above date	1 ○	2 ○	3 ○
2. Cytomegalovirus IgM antibody (CMV IgM)	(A.2.Date) CMVlgMDT _ _ /_ _ _ /_ _ _ _ ○ click to copy above date	1 ○ (A.2) CMVlgMDT	2 ○	3 ○
3. Epstein-Barr Virus IgG antibody (EBV IgG)	(A.3.Date) EBVlgDT _ _ /_ _ _ /_ _ _ _ ○ click to copy above date	1 ○ (A.3) EBVlgG	2 ○	3 ○
4. Hepatitis B Core antibody (HBc Ab)	(A.4.Date) HBcAbDT _ _ /_ _ _ /_ _ _ _ ○ click to copy above date	1 ○ (A.4) HBcAb	2 ○	3 ○
5. Hepatitis C antibody (HCV Ab)	(A.5.Date) HCVAbDT _ _ /_ _ _ /_ _ _ _ ○ click to copy above date	1 ○ (A.5) HCVAb	2 ○	3 ○
6. Hepatitis B surface antigen (HBsAg)	(A.6.Date) HBsAgDT _ _ /_ _ _ /_ _ _ _ ○ click to copy above date	1 ○ (A.6) HBsAg	2 ○	3 ○
7. Hepatitis B surface antibody (HBs Ab)	(A.7.Date) HBsAbDT _ _ /_ _ _ /_ _ _ _ ○ click to copy above date	1 ○ (A.7) HBsAb	2 ○	3 ○
8. HIV-I/II	(A.8.Date) HIVDT _ _ /_ _ _ /_ _ _ _ ○ click to copy above date	1 ○ (A.8) HIV	2 ○	3 ○
9. CMV by PCR	(A.9.Date) CMVPCRDT _ _ /_ _ _ /_ _ _ _ ○ click to copy above date	1 ○ (A.9) CMVPCR	2 ○	3 ○
10. EBV by PCR	(A.10.Date) EBVPCRDT _ _ /_ _ _ /_ _ _ _ ○ click to copy above date	1 ○ (A.10) EBVPCR	2 ○	3 ○

Subject ID ____ ____ -____ ____ - ____ ____ ____

A. SEROLOGY (Cont'd):

Infectious Disease	Date Sample Drawn (dd/mmm/yyyy)	Negative	Positive	Not Obtained
11. BKV by PCR (urine)	(A.11.Date) BKVurineDT _ _ /_ _ _ /_ _ _ _ ○ click to copy above date	1 ○ (A.11) BKVurnieDT	2 ○	3 ○
12. BKV by PCR (blood)	(A.12.Date) BKVbloodDT _ _ /_ _ _ /_ _ _ _ ○ click to copy above date	1 ○ (A.12) BKVblood	2 ○	3 ○

B. COMMENTS (optional): (B) Comments

Subject ID ____ ____ -____ ____ - ____ ____ ____

1. Date and time action was taken:

(1.a) ActionTakenDate a. Date: __ __/ __ __ __/ __ __ __ __ (dd/mmm/yyyy)

(1.b) ActionTakenTime b. Time: __ __ __ __ (hhmm - 24 hr clock) InitialAction

2. Action taken on the national transplant waitlist. Check only one (a-e): (2.a)

a. ☐ Initial Listing (2.a.i) ActionList
   - i ○ Active status (1)
   - ii ○ Inactive status (2)
   - iii ○ Listed without a status (3)

b. ☐ Status changed to Active (2.b) ActiveAction

c. ☐ Status changed to Inactive (2.c) InactiveAction
(select all that apply)

StatusInactiveSitePI i ☐ Site PI Unavailable (2.c.i)
StatusInactiveSiteStudy ii ☐ Site Study Coordinator Unavailable (2.c.ii)
StatusInactiveIsletLab iii ☐ Islet Lab Support Unavailable (2.c.iii)
StatusInactiveSubject iv ☐ Subject Unavailable (2.c.iv)
StatusInactiveTransientCon v ☐ Transient condition while on protocol waitlist (2.c.v)
StatusInactiveInstitution vi ☐ Institution Closed (i.e. holiday or other closure) (2.c.vi)
StatusInactiveOther vii ☐ Other reason: _____
(2.c.vii) (2.c.vii.Other) StatusInactiveTB

d. ☐ Removed from the national transplant waitlist (2.d) RemoveAction
(select all that apply)

(2.d.i) i ☐ Study consent withdrawn AND subject did not receive an islet transplant RemoveFromList

(2.d.ii) ii ☐ Subject recieved a study islet transplant (do not foresee subsequent islet transplants) RemoveFromListIsletTransplant

(2.d.iii) iii ☐ Subject became ineligible and subject did not receive an islet transplant RemoveFromListSubject

(2.d.iv) iv ☐ Other Reason: _____

RemoveFromListOther (2.d.iv.Other)RemoveFromListTB

(2.e) e. ☐ Other Action Taken: _____

OtherAction (2.e.Other)ActionTB