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 ____ ____ -____ ____ - ____ ____ ____

Report Number _____

A. ADVERSE EVENT

1. Date of adverse event ___ ___/___ ___ ___/___ ___ ___ ___ (A.1) EventDT
   (dd/mmm/yyyy)
2. Date site became aware of AE ___ ___/___ ___ ___/___ ___ ___ ___ (A.2) AwareAEDT
   (dd/mmm/yyyy)
3. Adverse Event Term (A.3) Keywords

4. Describe event or problem. (Include any details relating to diagnosis.) (A.4) EventSP

No **Yes**

5. ○ ○ Is this an exacerbation of a pre-existing condition (existing prior to enrollment)?
   0 1 (A.5)Exacerbation

6. Describe relevant tests/laboratory data, including dates. (A.6) TestsSP

7. Describe other relevant history, including preexisting medical conditions. (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (A.7) HistorySP

Subject ID ____ ____ -____ ____ - ____ ____ ____

Report Number _____

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

☐ Death: ___ ___/___ ___ ___/___ ___ ___ ___ (A.8.Date) OutDeathDT
(dd/mmm/yyyy)

☐ Life-threatening (A.8) OutLife
☐ Hospitalization - initial or prolonged (A.8) OutHosp
☐ Disability (A.8) OutDisability
☐ Congenital anomaly (A.8) OutCong
☐ Required intervention to prevent permanent impairment/damage (A.8) OutInterv
Important medical events as determined by the site PI or designee (A.8) OutMedEvent
☐ None of the above (non-serious AE) (A.8) OutNone

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: (A.8.a) AEtoSAEDT
__ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

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

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

10. If Outcome from item 8 was Death, was/will an autopsy be performed? (select one) (A.10) Autopsy
2○ No
1○ Yes ——— Please provide a de-identified copy to the DCC
3○ Unknown

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

Subject ID ____ ____ -____ ____ - ____ ____ ____

Report Number _____

No Yes

12. 0○ 1○ Was a study-related islet transplant procedure ever initiated for this subject? (A.12)IsletProcInit

a. Relationship to islet transplantation (A.12.a) IsletRelation

1○ Definite
2○ Probable
3○ Possible
4○ Unlikely
5○ Unrelated, Explain: _____ (A.12.a.text) IsletRelationSP

b. Action taken regarding islet transplantation (A.12.b)IsletAction

1○ Infusion not started
2○ None
3○ Interrupted but completed
4○ Prematurely terminated

No Yes ReceivedDrug

13. 0○ 1○ Has the subject ever received immunosuppression and/or infection prophylaxis? (A.13)

a. Relationship to immunosuppression/infection prophylaxis (A.13.a) RelationDrug

1○ Definite
2○ Probable
3○ Possible
4○ Unlikely RelationDrugSP
5○ Unrelated, Explain: _____ (A.13.a.text)

b. Action taken regarding immunosuppression/infection prophylaxis (A.13.b) ActionDrug

1○ None
2○ Dose reduced
3○ Interrupted
4○ Discontinued
5○ Dose increased

B. SUSPECT MEDICATION(S)

	Suspect Medication 1	Suspect Medication 2
1. Name	i. Islet Transplantation ☐ Purified Human Pancreatic Islets (check if ever received islets) (B.1.i) SMedName1Product ☐ Transplant Procedure (check if ever had islet transplant procedure initiated) (B.1.i) SMedName1TProc	Immunosuppression and infection prophylaxis (B.1.ii) SMedName2
2. Dose	(B.2.i) Dose1	
3. Therapy dates (if unknown, give best estimate)	i. Date of most recent islet transplantation (B.3.i) TherapyDT __ __ / __ __ __ / __ __ __ __ *(dd/mmm/yyyy)*	
4. Diagnosis for use	Type I Diabetes Mellitus (B.4.i) ~~Diagnosis1~~	Islet Transplant/Immunosuppression (B.4.ii) ~~Diagnosis2~~
5. Event abated after use stopped or dose reduced?	i. 0 ○ No 1 ○ Yes 2 ○ Doesn't apply (B.5.i) Abated1	ii. 0 ○ No 1 ○ Yes 2 ○ Doesn't apply (B.5.ii) Abated2
6. Event reappeared after reintroduction?	i. 0 ○ No 1 ○ Yes 2 ○ Doesn't apply (B.6.i) Reappeared1	ii. 0 ○ No 1 ○ Yes 2 ○ Doesn't apply (B.6.ii) Reappeared2
7. Lot number (B.7.i) Lot1	i.	
8. Expiration Date (if known)	i. __ __ / __ __ __ / __ __ __ __ (B.8.i) Exp1 *(dd/mmm/yyyy)*	

Subject ID ____ ____ -____ ____ - ____ ____ ____

Report Number _____

C. OTHER MEDICATIONS

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

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.

A. INDUCTION MEDICATIONS

Drug (Drug)	Date (StartDT)	Total Dose on this Date (mg) (Dose) Add new Entry
(1) ○ ATG (3) ○ Other ____	__/__/____ (dd/mmm/yyyy)	

B. SUBSEQUENT TRANSPLANT INDUCTION MEDICATION

Drug (Drug)	Date (StartDT)	Total Dose on this Date (mg) (Dose) Add new Entry
(2) ○ Daclizumab (30) ○ Basiliximab	__/__/____ (dd/mmm/yyyy)	

C. IMMUNUSUPPRESSIVE/ANTI-INFLAMMATORY MEDICATIONS

Drug (Drug)	Date (StartDT)	Total Dose on this Date (mg) (Dose) Add new Entry
(4) ○ Etanercept	__/__/____ (dd/mmm/yyyy)	

Sections A-C will be available for Induction only.
Section A will be available for first transplant only.
Section B will be available for second and third transplants only.

D. MAINTENANCE IMMUNOSUPPRESSION MEDICATIONS

Add new Entry

Drug (Drug)	**Total Dose (mg) / Day** (Dose)	Start Date (StartDT)	Stop Date (StopDT)
(6) ○ Tacrolimus (7) ○ Sirolimus (8) ○ Cyclosporine		__/__/____ (dd/mmm/yyyy)	__/__/____ (dd/mmm/yyyy)

E. TROUGH LEVELS

Drug (Drug)	Date of Draw (StartDT)	Trough Level (ng/mL) (Dose) Add new Entry
(25) ○ Tacrolimus (26) ○ Sirolimus (27) ○ Cyclosporine	__/__/____ (dd/mmm/yyyy)	☐ Undetectable (Undetectable)

F. OTHER MAINTENANCE IMMUNOSUPPRESSION MEDICATIONS

Add new Entry

Drug (Drug)	Total Dose (mg) / Day	Start Date (StartDT)	Stop Date (StopDT)
(9) ○ Mycophenolate sodium (10) ○ Mycophenolate mofetil (12) ○ Other	(Dose)	_ _/_ _ _/_ _ _ _ (dd/mmm/yyyy)	_ _/_ _ _/_ _ _ _ (dd/mmm/yyyy)

If Other, please complete Major Protocol Deviation form.

G. INFECTION PROPHYLAXIS MEDICATIONS

Add new entry

Drug (Drug)	Total Dose / Day	Start Date (StartDT)	Stop Date (StopDT)
(13) ○ TMP / SMX (SS=1 tab)* (14) ○ Clotrimazole (troche) (15) ○ Valganciclovir (mg) (29) ○ Other	(Dose)	_ _/_ _ _/_ _ _ _ (dd/mmm/yyyy)	_ _/_ _ _/_ _ _ _ (dd/mmm/yyyy)

*Single St rength TMP = 80mg SMX = 400mg

H. ANTICOAGULANT MEDICATIONS

Add new entry

Drug (Drug)	Total Dose (mg) / Day	Start Date (StartDT)	Stop Date (StopDT)
(17) ○ Enoxaparin (18) ○ Pentoxifylline (19) ○ Aspirin	(Dose)	_ _/_ _ _/_ _ _ _ (dd/mmm/yyyy)	_ _/_ _ _/_ _ _ _ (dd/mmm/yyyy)

I. COMMENTS (optional) (Comments)

Subject ID ____ ____ -____ ____ - ____ ____ ____

A. CITR CONSENT

	YES	NO	
1.	1○	0○	The subject consented to participate in CITR. (A.1) SubjectConsented
a.	1○	0○	The subject agreed to share their CIT data with CITR. (A.1.a) SubjectAgreed

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

Subject ID ____ ____ -____ ____ - ____ ____ ____

A. LYMPHOCYTOTOXIC CROSS-MATCH

1. Recipient Serum Date: __ __ / __ __ __ / __ __ __ __ *(dd/mmm/yyyy)*

2. Date Crossmatch Performed: __ __ / __ __ __ / __ __ __ __ (*dd/mmm/yyyy*) ⬭ (*click to copy date)*

.

No Yes

2a. ⬭ ⬭ Have you completed a major protocol deviation for this crossmatch (since the sample is >60 days old)?

⬭ Please complete the Major Protocol Deviation eCRF.

⬭ Continue to Question 3.

No Yes

3. ⬭ ⬭ 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. Enter new recipient serum date in Question 1.

⬭ Continue to Question 4.

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

	Cross-match	Results (Select one)	Method (Select one)
a.	Donor T Cell	○ Negative ○ Positive	○ NIH CDC ○ NIH ext CDC ○ Amos CDC ○ AHG CDC ○ ELISA ○ Flow Cytometry
b.	Donor B Cell	○ Negative ○ Positive	○ NIH CDC ○ NIH ext CDC ○ Amos CDC ○ AHG CDC ○ ELISA ○ Flow Cytometry
c.	Auto T Cell	○ Negative ○ Positive ○ Not Done	○ NIH CDC ○ NIH ext CDC ○ Amos CDC ○ AHG CDC ○ ELISA ○ Flow Cytometry
d.	Auto B Cell	○ Negative ○ Positive ○ Not Done	○ NIH CDC ○ NIH ext CDC ○ Amos CDC ○ AHG CDC ○ ELISA ○ Flow Cytometry

B. COMMENTS (optional)

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

A. TUBERCULOSIS TESTING

No Yes

1. 0 ○ 1 ○ Was TB Testing performed ?

(A.1)TBperformed

a. Date of TB Test ___ ___/___ ___ ___/___ ___ ___ ___ (A.1.a) VisitDT

(dd/mmm/yyyy)

b. Results (A.1.b) Results 2 ○ Positive 1 ○ Negative

c. Reason: 1 ○ Subject had a previous positive TB test

(A.1.c) TBreason 2 ○ Other

(A.1.c.other) OtherText

B. CHEST X-RAY

No **Yes**

1. 0○ 1○ Was a chest X-Ray performed? (B.1) Xray

   a. Date chest X-Ray was performed: ___ ___ / ___ ___ ___ / ___ ___ ___ ___
   (B.1.a) VisitDTa *(dd/mmm/yyyy)*

   b. Chest X-Ray interpreted as: (select one)(B.1.b) XRayInterp

   1○ Normal

   2○ Abnormal; clinically significant

   i.) Please specify abnormality: (B.1.b.i) XrayCLSP

   3○ Abnormal; not clinically significant

   ii.) Please specify abnormality: ((B.1.b.ii) XrayNCLSP

   c) Reason: (B.1.c) XrayReason

C. CARDIAC FUNCTION: ECG

No **Yes**

1. 0○ 1○ Was an ECG performed? (C.1) ECG

a. Date ECG was performed: ___ ___ / ___ ___ ___ / ___ ___ ___ ___
(C.1.a) ECGDT *(dd/mmm/yyyy)*

b. ECG interpreted as: (select one) (C.1.b) ECGInterp

1○ Normal

2○ Abnormal; clinically significant

i.) Please specify abnormality: (C.1.b.i) ECGCLSP

3○ Abnormal; not clinically significant

ii.) Please specify abnormality: (C.1.b.ii) ECGCLNSP

c. Reason: (C.1.c) ECGReason

D. CARDIAC STRESS TESTING/ANGIOGRAM

No Yes

1. 0○ 1○ Was a cardiac stress test or angiogram performed? (D.1) Stress

   a. Date test performed: ___ ___ / ___ ___ ___ / ___ ___ ___ ___
   (D.1.a) StressDT *(dd/mmm/yyyy)*

   b. Stress test interpreted as: (select one) (D.1.b) StressInterp

   1○ Normal

   2○ Other abnormality; clinically significant

   i.) Please specify abnormality: (D.1.b.i) StressCLSP

   3○ Other abnormality; not clinically significant

   ii.) Please specify abnormality: (D.1.b.ii) StressNCLSP

   c. Reason: (D.1.c) StressReason

E. ABDOMINAL ULTRASOUND

No Yes

1. 0○ 1○ Was an abdominal ultrasound performed? (E.1) AUPerformed

   a. Date ultrasound performed: ___ ___ / ___ ___ ___ / ___ ___ ___ ___
   (E.1.a) AUPerformedDT *(dd/mmm/yyyy)*

   b. Ultrasound interpreted as: (E.1.b) AUInterp

   1○ Normal

   2○ Abnormal; clinically significant

   i.) Please specify abnormality: (E.1.b.i) AbdominalCLSP

   3○ Abnormal; not clinically significant

   ii.) Please specify abnormality: (E.1.b.ii) AbdominalNCLSP

   c. Reason: (E.1.c) AbdominalReason

F. COMMENTS (optional) (F) Comments

Screening/Subject ID ____ ____ -____ ____ - ____ ____ ____

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

1. Type of consent (select one):

○ Enrollment

○ Post-randomization

2. a. Version number of consent document: ☐ N/A

b. Version date: __ __ / __ __ __ / __ __ __ __ ☐ N/A
(dd/mmm/yyyy)

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

	YES	NO	
4.	○	○	Does the consent contain long-term storage questions?
a.	○	○	The subject agreed to permit the collection and storage of blood samples for future research studies.
b.	○	○	The subject agreed to permit the collection and storage of blood samples for future genetic testing.

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

Subject ID ____ ____ -____ ____ - ____ ____ ____

A. PRA (METHOD MUST BE FLOW)

1. Date of test ___ ___ / ___ ___ ___ / ___ ___ ___ ___ ☐ *Not done*
(A.1) PRADT *(dd/mmm/yyyy)* TESTND

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

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

2 ○ Positive 1 ○ Negative 3 ○ 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) PRAIDefined1 - (A.2.iv) PRAIDefined12

☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐

3. Class II Antibody Screen (A.3) PRAIIResults

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

2 ○ Positive 1 ○ Negative 3 ○ Not Performed

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) PRAIIDefined1 - (A.3.iv) PRAIIDefined12

☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐

Subject ID ____ ____ -____ ____ - ____ ____ ____

B. Comments:

(B) 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

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

   1 ○ Yes
   2 ○ No
   3 ○ Unknown

2. Has the subject been hospitalized for DKA within the last 12 months? (select one) (B.2) HospDKA

   1 ○ Yes
   - a. Specify number of hospitalizations in the last 12 months ____ (B.2.a) HospDKAsp

   2 ○ No
   3 ○ Unknown

C. IODINE ALLERGY

	No	Yes		
1.	0 ○	1 ○	Does the subject have a history of allergies to seafood or iodine-containing products?	(C.1) allergies

Do not perform GFR.

D. CIPROFLOXACIN ALLERGY

	No	Yes		
1.	0 ○	1 ○	Is the subject allergic to ciprofloxacin?	(D.1) AllergicCipro

Subject unable to receive islet transplant with ciprofloxacin added.

E. MEDICAL HISTORY

		Assessment	Any significant medical history? No	Any significant medical history? Yes	If Yes, please give details.	
(E.1)	1.	Skin skin	0 O	1 O	skinSP	(E.1.text)
(E.2)	2.	Head, Eyes, Ears, Nose, Throat head	0 O	1 O	headSP	(E.2.text)
(E.3)	3.	Respiratory Resp	0 O	1 O	respSP	(E.3.text)
(E.4)	4.	Cardiovascular Card	0 O	1 O	cardSP	(E.4.text)
(E.5)	5.	Gastrointestinal Gast	0 O	1 O	gastSp	(E.5.text)
(E.6)	6.	Endocrine/Metabolic (except Diabetes) Endo	0 O	1 O	endoSP	(E.6.text)
(E.7)	7.	Genitourinary/Reproductive Geni	0 O	1 O	geniSP	(E.7.text)
(E.8)	8.	Neurological Neur	0 O	1 O	neurSP	(E.8.text)
(E.9)	9.	Blood/Lymphatic Blood	0 O	1 O	bloodSP	(E.9.text)
(E.10)	10.	Musculoskeletal Muscu	0 O	1 O	muscuSP	(E.10.text)
(E.11)	11.	Hepatic/Biliary Hepatic	0 O	1 O	hepaticSP	(E.11.text)
(E.12)	12.	Allergies/Immunologic Allerg	0 O	1 O	AllergSp	(E.12.text)
(E.13)	13.	Psychological/Psychiatric Psych	0 O	1 O	psychSp	(E.13.text)
(E.14)	14.	Other Other		1 O	otherSP	(E.14.text)

F. COMMENTS (optional) (F) 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. 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 ___ ___ ___ / ___ ___ ___ (mm Hg) (A.4.1) BP1 (A.4.2) BP2
5. Weight ____ (kg) (A.5) Weight
6. Height ____ (cm) (A.6) Height
7. BMI ____ (kg/m²) [This will be autocalculated on the web.] (A.7) BMI

B. 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	○ 1	○ 2	○ 3		(B.11.a) OtherSP

(B.11.Name) OtherSpecify

Subject ID ____ ____ -____ ____ - ____ ____ ____

C. PHYSICAL EXAMINATION

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

(C.11.Name) OtherSpecify2

D. COMMENTS (optional) (D) 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

☐ Subject is not of childbearing potential (Available for CIT04 only)

(A.1.d.ii) NotChildbearing

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

If Question 1c is 'positive' post-randomization, 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 four criteria is answered YES, begin **Reduced Follow-Up Schedule.**

	No	Yes	
1.	0 ○	1 ○	The subject is unwilling or unable to comply with the protocol. (A.1) Protocol
2.	0 ○	1 ○	The investigator believes that the study treatment is no longer in the best interest of the subject. (A.2) Investigator
3.	0 ○	1 ○	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.3) GraftFailure
4.	0 ○	1 ○	An unexpected related serious adverse event. (A.4) SAE

B. COMMENTS (optional) (B) Comments

A. INCLUSION CRITERIA

Subjects must meet all of the following criteria to be considered eligible for randomization between protocols.

	No	Yes	
1.0	○	1 ○	Male and female patients age 18 to 65 years of age. (A.1) Age
2.0	○	1 ○	Ability to provide written informed consent. (A.2) Consent
3.0	○	1 ○	Mentally stable and able to comply with the procedures of the study protocol. (A.3) Comply
4.0	○	1 ○	Clinical history compatible with type 1 diabetes with onset of disease at < 40 years of age, insulin-dependence for ≥ 5 years at the time of enrollment, and a sum of patient age and insulin dependent diabetes duration of ≥ 28. (A.4) Type1
5.0	○	1 ○	Absent stimulated C-peptide (<0.3ng/mL) in response to a mixed meal tolerance test (Boost® 6 mL/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 ○	Involvement in intensive diabetes management defined as self monitoring of glucose values no less than a mean of three times each day averaged over each week and by the administration of three or more insulin injections each day or insulin pump therapy. 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.6) Management
7.0	○	1 ○	At least one episode of severe hypoglycemia in the 12 months prior to study enrollment. (A.7) Hypoglycemia

A. INCLUSION CRITERIA *(continued)*

No **Yes** (A.8) Clarke

8. 0 ○ 1 ○ At least one of the following: (check all that apply)

___

a. ☐ Reduced awareness of hypoglycemia as defined by a Clarke score of 4 or more or a HYPO score greater than or equal to the 90th percentile (1047) during the screening period and within the last 6 months prior to randomization;

(A.8.a) Awareness

b. ☐ Marked glycemic lability characterized by wide swings in blood glucose despite optimal diabetes therapy and defined by a glycemic lability index (LI) score greater than or equal to the 90th percentile (433 $mmol/L^2/h \cdot wk^{-1}$) during the screening period and within the last 6 months prior to randomization;

(A.8.b) Glycemic

c. ☐ A composite of a Clarke score of 4 or more and a HYPO score greater than or equal to the 75th percentile (423) and a LI greater than or equal to the 75th percentile (329) during the screening period and within the last 6 months prior to randomization.

(A.8.c) Composite

B. EXCLUSION CRITERIA

Subjects who meet any of the following criteria are not eligible for randomization between protocols.

	No	Yes	
1.	0○	1○	BMI >30 kg/m^2 or patient weight ≤ 50 kg. (B.1) BMI
2.	0○	1○	Insulin requirement of > 1.0 IU/kg/day or < 15 U/day. (B.2) Insulin
3.	0○	1○	HbA1c > 10%. (B.3) HbA1c
4.	0○	1○	Untreated proliferative diabetic retinopathy. (B.4) Retinopathy
5.	0○	1○	Blood Pressure: SBP > 160 mmHg or DBP > 100 mmHg. (B.5) BP
6.	0○	1○	Measured glomerular filtration rate (using iohexol) of <80 mL/min/1.73m^2 (or for subjects with an iodine allergy, calculated using the subject's measured serum creatinine and Chronic Kidney Disease Epidemiology Collaboration [CKD-EPI] equation). Strict vegetarians (vegans) with a calculated GFR < 70 mL/min/1.73m^2 are excluded. The absolute (raw) GFR value will be used for subjects with body surface areas > 1.73 m^2. (B.6) Glomerular
7.	0○	1○	Presence or history of macroalbuminuria (>300 mg/g creatinine). (B.7) Macroalbuminuria
8.	0○	1○	Presence or history of panel-reactive anti-HLA antibodies above background by flow cytometry. (B.8) AntiHLA
9.	0○	1○	**For female subjects:** Positive pregnancy test, presently breast-feeding, or unwillingness to use effective contraceptive measures for the duration of the study and 4 months after discontinuation. **For male subjects**: 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.9) Pregnancy
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.10) Infection
11.	0○	1○	Negative screen for Epstein-Barr Virus (EBV) by IgG determination. (B.11) EBV

B. EXCLUSION CRITERIA *(continued)*

	No	Yes	
12.	0 ○	1 ○	Invasive aspergillus, histoplasmosis, or coccidoidomycosis infection within one year prior to study enrollment. (B.12) Aspergillus
13.	0 ○	1 ○	Any history of malignancy except for completely resected squamous or basal cell carcinoma of the skin. (B.13) Malignancy
14.	0 ○	1 ○	Known active alcohol or substance abuse. (B.14) AlcAbuse
15.	0 ○	1 ○	Baseline Hb below the lower limits of normal at the local laboratory; lymphopenia (<1000/ uL), neutropenia (<1500/uL), or thrombocytopenia (platelets <100,000/ uL). Participants with lymphopenia are allowed if the investigator determines there is no additional risk and obtains clearance from a hematologist. (B.15) Hgb
16.	0 ○	1 ○	A history of Factor V deficiency. (B.16) FactorV
17.	0 ○	1 ○	Any coagulopathy or medical condition requiring long-term anticoagulant therapy (e.g., warfarin) after transplantation (low-dose aspirin treatment is allowed) or patients with an INR > 1.5. (B.17) Coagulopathy
18.	0 ○	1 ○	Severe co-existing cardiac disease, characterized by any one of these conditions:(B.18) Cardiac a) ☐ recent myocardial infarction (within past 6 months). (B.18.a) Myocardial b) ☐ evidence of ischemia on functional cardiac exam within the last year. (B.18.b) Ischemia c) ☐ left ventricular ejection fraction <30%. (B.18.c) Ventricular
19.	0 ○	1 ○	Persistent elevation of liver function tests at the time of study entry. Persistent SGOT (AST), SGPT (ALT), Alk Phos or total bilirubin, with values > 1.5 times normal upper limits will exclude a patient. (B.19) LiverFunction
20.	0 ○	1 ○	Symptomatic cholecystolithiasis. (B.20) Cholecyst
21.	0 ○	1 ○	Acute or chronic pancreatitis. (B.21) Pancreatitis
22.	0 ○	1 ○	Symptomatic peptic ulcer disease. (B.22) Peptic
23.	0 ○	1 ○	Severe unremitting diarrhea, vomiting or other gastrointestinal disorders potentially interfering with the ability to absorb oral medications. (B.23) Diarrhea
24.	0 ○	1 ○	Hyperlipidemia despite medical therapy (fasting LDL cholesterol > 130 mg/dL, treated or untreated; and/or fasting triglycerides > 200mg/dL). (B.24) Hyperlipidemia
25.	0 ○	1 ○	Receiving treatment for a medical condition requiring chronic use of systemic steroids, except for the use of ≤ 5mg prednisone daily, or an equivalent dose of hydrocortisone, for physiological replacement only. (B.25) Treatment

B. EXCLUSION CRITERIA *(continued)*

	No	Yes	
26.	0○	1○	Treatment with any anti-diabetic medication other than insulin within 4 weeks of enrollment. (B.26) AnitDiabetic
27.	0○	1○	Use of any investigational agents within 4 weeks of enrollment. (B.27) OtherAgents
28.	0○	1○	Administration of live attenuated vaccine(s) within 2 months of enrollment. (B.28) Vaccine
29.	0○	1○	Any medical condition that, in the opinion of the investigator, will interfere with safe participation in the trial. (B.29) MedCondition
30.	0○	1○	Treatment with any immunosuppressive regimen at the time of enrollment. (B.30) Immunosuppressive
31	0○	1○	A previous islet transplant. (B.31) PreIslet
32.	0○	1○	A previous pancreas transplant, unless the graft failed within the first week due to thrombosis, followed by pancreatectomy and the transplant occurred more than 6 months prior to enrollment. (B.32) PrePancreas

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. RETINOPATHY

	No (0)	Yes (1)	
1.	○	○	Was an eye exam completed? (A.1) (EyeExam)

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

- 1 ○ Not present
- 2 ○ Mild nonproliferative
- 3 ○ Moderate nonproliferative
- 4 ○ Severe nonproliferative
- 5 ○ Proliferative

	No (0)	Yes (1)	
2.	○	○	Was a photo of the retina completed? (A.2) (photo)

a. Was the retinopathy photo sent to the Central Laboratory? (A.2.a) (IsPhotoSent)

1 ○ **Yes** - Date Sent: __ __ /__ __ __ / __ __ __ __ (A.2.a.i)
(dd/mmm/yyyy) (PhotoSentDT)

0 ○ **No** - Please Comment Below

b. Reason _____ (A.2.b) (PhotoReason)

B. COMMENTS (optional) (B) (comment)

A. INCLUSION CRITERIA

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

	No (0)	Yes (1)	
1.	○	○	Male and female patients age 18 to 65 years of age. (A.1) (Age)
2.	○	○	Ability to provide written informed consent. (A.2) (Consent)
3.	○	○	Mentally stable and able to comply with the procedures of the study protocol. (A.3) (Comply)
4.	○	○	Clinical history compatible with type 1 diabetes with onset of disease at < 40 years of age, insulin-dependence for ≥ 5 years at the time of enrollment, and a sum of patient age and insulin dependent diabetes duration of ≥ 28. (A.4) (Type1)
5.	○	○	Absent stimulated C-peptide (<0.3ng/mL) in response to a mixed meal tolerance test (Boost® 6 mL/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.	○	○	Involvement in intensive diabetes management defined as self monitoring of glucose values no less than a mean of three times each day averaged over each week and by the administration of three or more insulin injections each day or insulin pump therapy. 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.6) (Management)
7.	○	○	At least one episode of severe hypoglycemia in the 12 months prior to study enrollment. (A.7) (Hypoglycemia)

Screening ID ____ ____ -____ ____ - ____ ____ ____

A. INCLUSION CRITERIA *(continued)*

	No	Yes	
8.	○	○	At least one of the following: (check all that apply) (A.8) (Clarke)
	(0)	(1)	

a. ☐ Reduced awareness of hypoglycemia as defined by a Clarke score of 4 or more or a HYPO score greater than or equal to the 90th percentile (1047) during the screening period and within the last 6 months prior to randomization; (A.8.a) (Awareness)

b. ☐ Marked glycemic lability characterized by wide swings in blood glucose despite optimal diabetes therapy and defined by a glycemic lability index (LI) score greater than or equal to the 90th percentile (433 mmol/L^2/h·wk^{-1}) during the screening period and within the last 6 months prior to randomization; (A.8.b) (Lability)

c. ☐ A composite of a Clarke score of 4 or more and a HYPO score greater than or equal to the 75th percentile (423) and a LI greater than or equal to the 75th percentile (329) during the screening period and within the last 6 months prior to randomization.

(A.8.c) (Composite)

B. EXCLUSION CRITERIA

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

	No (0)	Yes (1)	
1.	○	○	BMI >30 kg/m^2 or patient weight ≤ 50 kg. (B.1) (BMI)
2.	○	○	Insulin requirement of > 1.0 IU/kg/day or < 15 U/day. (B.2) (Insulin)
3.	○	○	HbA1c > 10%. (B.3) (HbA1c)
4.	○	○	Untreated proliferative diabetic retinopathy. (B.4) (Retinopathy)
5.	○	○	Blood Pressure: SBP > 160 mmHg or DBP > 100 mmHg. (B.5) (BP)
6.	○	○	Measured glomerular filtration rate (using iohexol) of <80 mL/min/1.73m^2 (or for subjects with an iodine allergy, calculated using the subject's measured serum creatinine and the Chronic Kidney Disease Epidemiology Collaboration [CKD-EPI] equation). Strict vegetarians (vegans) with a calculated GFR < 70 mL/min/1.73m^2 are excluded. The absolute (raw) GFR value will be used for subjects with body surface areas > 1.73 m2. (B.6)(GFR)
7.	○	○	Presence or history of macroalbuminuria (>300 mg/g creatinine). (B.7) (MacroAlb)
8.	○	○	Presence or history of panel-reactive anti-HLA antibodies above background by flow cytometry. (B.8) (AntiHLA)
9.	○	○	**For female subjects:** Positive pregnancy test, presently breast-feeding, or unwillingness to use effective contraceptive measures for the duration of the study and 4 months after discontinuation. (B.9) (PregTest) **For male subjects**: 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.
10.	○	○	Presence or history of active infection including hepatitis B, hepatitis C, HIV, or tuberculosis (TB). Subjects with laboratory evidnece of active infection are excluded even in the absence of active infection.. (B.10) (Infection)
11.	○	○	Negative screen for Epstein-Barr Virus (EBV) by IgG determination. (B.11) (EBV)

B. EXCLUSION CRITERIA *(continued)*

	No	Yes	
12.	○ (0)	○ (1)	Invasive aspergillus, histoplasmosis, or coccidoidomycosis infection within one year prior to study enrollment. (B.12) (aspergillus)
13.	○ (0)	○ (1)	Any history of malignancy except for completely resected squamous or basal cell carcinoma of the skin. (B.13) (malignancy)
14.	○ (0)	○ (1)	Known active alcohol or substance abuse. (B.14) (AlcAbuse)
15.	○ (0)	○ (1)	Baseline Hb below the lower limits of normal at the local laboratory; lymphopenia (<1000/ uL), neutropenia (<1500/uL), or thrombocytopenia (platelets <100,000/ uL). Participants with lymphopenia are allowed if the investigator determines there is no additional risk and obtains clearance from a hematologist. (B.15) (Hgb)
16.	○ (0)	○ (1)	A history of Factor V deficiency. (B.16) (FactorV)
17.	○ (0)	○ (1)	Any coagulopathy or medical condition requiring long-term anticoagulant therapy (e.g., warfarin) after transplantation (low-dose aspirin treatment is allowed) or patients with an INR > 1.5. (B.17) (coagulopathy)
18.	○ (0)	○ (1)	Severe co-existing cardiac disease, characterized by any one of these conditions:(B.18)(Cardiac) a) ☐ recent myocardial infarction (within past 6 months). (B.18.a)(Infarction) b) ☐ evidence of ischemia on functional cardiac exam within the last year.(B.18.b) (Ischemia) c) ☐ left ventricular ejection fraction <30%. (B.18.c) (Ejection)
19.	○ (0)	○ (1)	Persistent elevation of liver function tests at the time of study entry. Persistent SGOT (AST), SGPT (ALT), Alk Phos or total bilirubin, with values > 1.5 times normal upper limits will exclude a patient. (B.19) (liver)
20.	○ (0)	○ (1)	Symptomatic cholecystolithiasis. (B.20) (cholecyst)
21.	○ (0)	○ (1)	Acute or chronic pancreatitis. (B.21) (pancreatitis)
22.	○ (0)	○ (1)	Symptomatic peptic ulcer disease. (B.22) (peptic)
23.	○ (0)	○ (1)	Severe unremitting diarrhea, vomiting or other gastrointestinal disorders potentially interfering with the ability to absorb oral medications. (B.23) (diarrhea)
24.	○ (0)	○ (1)	Hyperlipidemia despite medical therapy (fasting LDL cholesterol > 130 mg/dL, treated or untreated; and/or fasting triglycerides > 200mg/dL). (B.24) (Hyperlipidemia)
25.	○ (0)	○ (1)	Receiving treatment for a medical condition requiring chronic use of systemic steroids, except for the use of ≤ 5mg prednisone daily, or an equivalent dose of hydrocortisone, for physiological replacement only. (B.25) (treatment)

B. EXCLUSION CRITERIA *(continued)*

	No	Yes	
26.	○ (0)	○ (1)	Treatment with any anti-diabetic medication other than insulin within 4 weeks of enrollment. (B.26) (Hypoglycemic)
27.	○ (0)	○ (1)	Use of any investigational agents within 4 weeks of enrollment. (B.27) (OtherAgents)
28.	○ (0)	○ (1)	Administration of live attenuated vaccine(s) within 2 months of enrollment. (B.28) (vaccine)
29.	○ (0)	○ (1)	Any medical condition that, in the opinion of the investigator, will interfere with safe participation in the trial. (B.29) (MedCondition)
30.	○ (0)	○ (1)	Treatment with any immunosuppressive regimen at the time of enrollment. (B.30) (Immoumnosuppressive)
31.	○ (0)	○ (1)	A previous islet transplant. (B.31) (IsletTransplant)
32.	○ (0)	○ (1)	A previous pancreas transplant, unless the graft failed within the first week due to thrombosis, followed by pancreatectomy and the transplant occurred more than 6 months prior to enrollment. (B.32) (previousTransplant)

Subject ID ____ ____ -____ ____ - ____ ____ ____

A. REQUIREMENTS FOR A SECOND TRANSPLANT

(Questions 1-10 are mandatory)

	No (0)	Yes (1)	
1.	○	○	Subject received ≥ 5000 IE/kg with the first transplant, but failed to achieve or maintain insulin independence *[if No, Ineligible]*. (A.1) (InsulinIndependence)
2.	○	○	Subject has been compliant with study monitoring and prescribed immunosuppressive therapy *[if No, Ineligible]*. (A.2) (ComplaintMonitoring)
3.	○	○	Subject has no unresolved SAEs *[if No, Ineligible]*. (A.3) (UnresolvedSAEs)
4.	○	○	No evidence of progressive renal dysfunction, with blood creatinine rising above 2.0 mg/dL (177 umol/L) *[if No, Ineligible]*. (A.4) (NoProgressive)
5.	○	○	No evidence of hypersensitization, allergic responses, or other potentially serious drug reactions to medications required by the protocol *[if No, Ineligible]*.(A.5) (NoHypersensitization)
6.	○	○	PRA ≤ 50% by flow cytometry (assessment performed locally) and the alloantibody specificity not cross-reactive with antigen(s) present in the subsequent islet preparation in order to avoid unacceptable antigen(s) *[if No, Ineligible]*. (A.6) (PRA)
7.	○	○	Subject has no medical condition that, in the opinion of the investigator, would interfere with a safe and successful islet transplant *[if No, Ineligible]*. (A.7) MedicalCondition
8.	○	○	75 ± 5 day visit and metabolic assessments have been completed *[If No, 8a must be Yes, and there must be a date in 8ai1 to be eligible. Otherwise Ineligible]*. (A.8) (MetabolicAssessments)

a. ○ (0) ○ (1) The subject has confirmed graft failure (basal and stimulated c-peptide < 0.3 ng/mL). (A.8.a) GraftFailure

i. ○ (0) ○ (1) The Steering Committee has reviewed and given final approval for a second infusion. (A.8.a.i) SteeringCommittee

1. Date of SC approval: __ __/ __ __ __ / __ __ __ __ (A.8.a.1)SCApprovalDate *(dd/mmm/yyyy)*

9.	○ (0)	○ (1)	It has been ≤ 8 months since the first islet transplant. *[if No, Ineligible]*. (A.9) TwelveMonths
10.	○ (0)	○ (1)	Either basal or stimulated C-peptide levels are ≥ 0.3 ng/mL (0.1 nmol/L)*[If No, 10a must be Yes, and there must be a date in 10ai to be eligible. Otherwise Ineligible]*.. (A.10) CPeptide

a. ○ (0) ○ (1) The Steering Committee has reviewed and given final approval for a second infusion. (A.10.a) SCApproval

i. Date of SC approval: __ __/ __ __ __ / __ __ __ __ (A.10.a.i) SCApprovalDT *dd/mmm/yyyy)*

B. COMMENTS (optional) (B) Comments

Subject ID ____ ____ -____ ____ - ____ ____ ____

A. SEROLOGY

DrawDT (DrawDT)

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

	Infectious Disease	Date Sample Drawn (dd/mmm/yyyy)	Negative	Positive	Not Obtained	
(A.1.date) CMVIgGDT	1. Cytomegalovirus IgG antibody (CMV IgG)	_ _ /_ _ _ /_ _ _ _ ○ click to copy above date	1 ○	2 ○	3 ○	CMVIgG (A.1)
(A.2.date) CMVIgMDT	2. Cytomegalovirus IgM antibody (CMV IgM)	_ _ /_ _ _ /_ _ _ _ ○ click to copy above date	1 ○	2 ○	3 ○	CMVIgM (A.2)
(A.3.date) EBVIgGDT	3. Epstein-Barr Virus IgG antibody (EBV IgG)	_ _ /_ _ _ /_ _ _ _ ○ click to copy above date	1 ○	2 ○	3 ○	EBVIgG (A.3)
(A.4.date) HBcAbDT	4. Hepatitis B Core antibody (HBc Ab)	_ _ /_ _ _ /_ _ _ _ ○ click to copy above date	1 ○	2 ○	3 ○	HBcAb (A.4)
(A.5.date) HCVAbDT	5. Hepatitis C antibody (HCV Ab)	_ _ /_ _ _ /_ _ _ _ ○ click to copy above date	1 ○	2 ○	3 ○	HCVAb (A.5)
(A.6.date) HBsAgDT	6. Hepatitis B surface antigen (HBsAg)	_ _ /_ _ _ /_ _ _ _ ○ click to copy above date	1 ○	2 ○	3 ○	HBsAg (A.6)
(A.7.date) HBsAbDT	7. Hepatitis B surface antibody (HBs Ab)	_ _ /_ _ _ /_ _ _ _ ○ click to copy above date	1 ○	2 ○	3 ○	HBsAb (A.7)
(A.8.date) HTLVDT	8. HTLV-I/II	_ _ /_ _ _ /_ _ _ _ ○ click to copy above date	1 ○	2 ○	3 ○	HTLV (A.8)
(A.9.date) HIVDT	9. HIV-I/II	_ _ /_ _ _ /_ _ _ _ ○ click to copy above date	1 ○	2 ○	3 ○	HIV (A.9)
(A.10.date) CMVPCRDT	10. CMV by PCR	_ _ /_ _ _ /_ _ _ _ ○ click to copy above date	1 ○	2 ○	3 ○	CMVPCR (A.10)
(A.11.date) EBVPCRDT	11. EBV by PCR	_ _ /_ _ _ /_ _ _ _ ○ click to copy above date	1 ○	2 ○	3 ○	EBVPCR (A.11)

Subject ID ____ ____ -____ ____ - ____ ____ ____

B. COMMENTS (optional): (B) Comments

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) LastVisitDT

3. Indicate the primary reason the subject will no longer be followed: (select one) (3) Reason

1 ○ Subject completed study procedures per protocol

2 ○ Subject withdrew consent

3 ○ Lost to follow-up (Unable/unwilling to travel/moved from area/unable to locate)

4 ○ Subject death

Complete the Adverse Event form

5 ○ Screening Eligibility form completed, indicating a "screening success", but subject did not actually meet eligibility criteria

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

6 ○ Screening Eligibility form completed, indicating a "screening success", but the subject became ineligible while on wait list

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)

7 ○ Subject randomized but did not actually meet randomization eligibility criteria

Do NOT complete this Study Termination eCRF if the subject received immunosuppression medications post-randomization in preparation for a CIT Islet Transplant.

Complete the Major Protocol Deviation form to explain

8 ○ Other

(3.Specify) OtherSP

Please specify: _____

4. Comments (optional): (4) Comments

Subject ID ____ ____ -____ ____ - ____ ____ ____

A. REQUIREMENTS FOR A THIRD TRANSPLANT

Questions 1-11 must be answered YES in order for the subject to be eligible for a third islet transplant.

	No (0)	Yes (1)	
1.	○	○	Subject received > 4000 IE/kg with the second transplant, but remains dependent on insulin for longer than one month after the second transplant. (A.1) (InsulinDep)
2.	○	○	There is evidence of partial graft function. (A.2) (GraftFunction)
3.	○	○	The CIT PIs, Site PIs and the Steering Committee have determined that there were no relevant protocol deviations at the site. (A.3) (Deviation)
			a. Date of SC approval: __ __/ __ __ __ / __ __ __ _ (A.3.a)(DeviationDT) *(dd/mmm/yyyy)*
4.	○	○	The subject has been compliant with study monitoring and prescribed immunosuppressive therapy. (A.4) (Compliant)
5.	○	○	No evidence of a serious and life-threatening infection, adverse event or other condition that precludes attempting an intraportal injection or continuation of the post-transplant treatment regimen. (A.5) (SAE)
6.	○	○	No evidence of post-transplant lymphoproliferative disorder (PTLD). (A.6) (PTLD)
7.	○	○	No evidence of progressive renal dysfunction, with blood creatinine rising above 2.0 mg/dL (177 umol/L). (A.7) (RenalDysfunction)
8.	○	○	No evidence of hypersensitization, allergic responses or other potentially serious drug reactions to medications required by the protocol. (A.8) (Reactions)
9.	○	○	No evidence of abnormal liver ultrasound and LFTs within1.5 times the upper limit of the normal range. (A.9) (AbnLiver)
10.	○	○	Subject has not completed 8 months follow-up post-first transplant. (A.10) (Followup)
11.	○	○	PRA ≤ 50% by flow cytometry (assessment performed locally) and the alloantibody specificity not cross-reactive with antigen(s) present in the subsequent islet preparation in order to avoid unacceptable antigen(s). (A.11) (PRA)

If any of these questions is answered NO, the user will receive a message saying, "Subject is INELIGIBLE for re-transplant."

(B) (Comments)

B. COMMENTS (optional)

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