

Subject ID _____ - _____ - _____

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A. INVESTIGATIONAL AGENT

Drug	Date	Total Dose on this Date (mg)
<input type="radio"/> Belatacept	<div> <div>__ / __ / __</div> <div>(dd/mm/yyyy)</div> </div>	<div></div>

Add New Entry

B. INDUCTION MEDICATION

Drug	Date	Total Dose on this Date (mg)
<input type="radio"/> Daclizumab	<div> <div>__ / __ / __</div> <div>(dd/mm/yyyy)</div> </div>	<div></div>
<input type="radio"/> Basiliximab		

Add New Entry

*Section A & B will be available for Induction only.***C. MAINTENANCE IMMUNOSUPPRESSION MEDICATIONS**

Drug	Total Dose (mg)/ Day	Start Date	Stop Date
<input type="radio"/> Tacrolimus	<div></div>	<div> <div>__ / __ / __</div> <div>(dd/mm/yyyy)</div> </div>	<div> <div>__ / __ / __</div> <div>(dd/mm/yyyy)</div> </div>
<input type="radio"/> Mycophenolate mofetil			
<input type="radio"/> Other			

Add New Entry

If Other, please complete Major Protocol Deviation form.**D. TROUGH LEVELS**

Drug	Date of Draw	Trough Level
<input type="radio"/> Tacrolimus	<div> <div>__ / __ / __</div> <div>(dd/mm/yyyy)</div> </div>	<div> <div></div> (ng/mL) <input type="checkbox"/> Undetectable </div>

Add New Entry

Subject ID

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E. INFECTION PROPHYLAXIS MEDICATIONS

Add new Entry

Drug	Total Dose / Day	Start Date	Stop Date
<input type="radio"/> TMP/SMX (SS=1 tab)*	<input type="text"/>	<input type="text"/> dd/mm/yyyy	<input type="text"/> dd/mm/yyyy
<input type="radio"/> Valganciclovir (mg)			
<input type="radio"/> Other			

* single strength TMP = 80 mg SMX = 400 mg

F. ANTICOAGULANT MEDICATIONS

Add new Entry

Drug	Total Dose (mg) / Day	Start Date	Stop Date
<input type="radio"/> Enoxaparin	<input type="text"/>	<input type="text"/> (dd/mm/yyyy)	<input type="text"/> (dd/mm/yyyy)
<input type="radio"/> Pentoxifylline			
<input type="radio"/> Aspirin			

G. COMMENTS (optional)

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A. CRITERIA FOR PREMATURE DISCONTINUATION OF STUDY TREATMENT

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

No Yes

1. ☐ ☐ The subject is unwilling or unable to comply with the protocol.
2. ☐ ☐ The investigator believes that the study treatment is no longer in the best interest of the subject.
3. ☐ ☐ Graft Failure: Islet cell allograft failure will be defined as absence of insulin production by transplanted islets, as evidenced by absence of C-peptide. This will be determined by (1) undetectable C-peptide on random testing, followed by (2) undetectable C-peptide at baseline, and at 60 and 90 minutes after MMTT.
4. ☐ ☐ Any clinical adverse event, laboratory abnormality, or intercurrent illness which, in the opinion of the investigator, indicates that continued treatment with study therapy is not in the best interest of the subject. The agent(s) to which the event is attributed will be discontinued.
5. ☐ ☐ The subject becomes pregnant.
6. ☐ ☐ Missing 2 consecutive belatacept infusions.
7. ☐ ☐ The development of belatacept is terminated by the manufacturer (BMS).
8. ☐ ☐ The subject is imprisoned or compulsorily detained for the treatment of either a psychiatric or physical illness (e.g., infectious disease).

B. COMMENTS (optional)

Subject ID _____ - _____ - _____

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A. Was Belatacept trough level; Visits 04 - 30 (Subs Tx Days 4, 7, 75, and 365), and /or Immunogenicity sample; Visits 03, 14, 21, 27 (Subs Tx Day 365) and 4 weeks and 8 weeks post last dose of belatacept, obtained?

	No	Yes
1.	<input type="radio"/>	<input type="radio"/>
a. Date of draw		<div>____/____/____ (dd/mm/yyyy)</div>
b. Time of draw		<div>____:____ (0000-2359)</div>
c. Was Belatacept trough level aliquot obtained ?		<input type="radio"/> yes <input type="radio"/> no If no for visits 04 -30 (Subs Tx days 4, 7, 75, and 365), please comment <div></div>
d. Was Immunogenicity sample aliquot obtained?		<input type="radio"/> yes <input type="radio"/> no If no for visits 03, 14, 21, 27 (Subs Tx Day 365), and 4 weeks and 8 weeks post last dose of belatacept, please comment <div></div>
Reason:		<div></div>

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Report Number _____

A. ADVERSE EVENT1. Date of adverse event _____/_____/_____
(dd/mm/yyyy)2. Date site became aware of AE _____/_____/_____
(dd/mm/yyyy)

3. Adverse Event Term

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

No Yes5. ☐ ☐ 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.)

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Report Number _____

8. Outcomes attributed to adverse event (Check all that apply)

- ☐ 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

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 - If resolved, give date of resolution _____
(dd/mmm/yyyy)

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Report Number _____

- No** **Yes**
12. ☐ ☐ Was a study-related islet transplant procedure 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 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. ☐ ☐ Has the subject received the investigational drug, Belatacept?
- _____ a. Relationship to Belatacept
- ☐ Definite
- ☐ Probable
- ☐ Possible
- ☐ Unlikely
- ☐ Unrelated, Explain: _____
- b. Action taken regarding Belatacept
- ☐ None
- ☐ Dose reduced
- ☐ Interrupted
- ☐ Discontinued
- ☐ Dose increased

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Report Number _____

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B. SUSPECT MEDICATION(S)

	Suspect Medication 1	Suspect Medication 2	Suspect Medication 3
1. Name	i. Islet Transplantation (check all that may apply) <input type="checkbox"/> Islet Product <input type="checkbox"/> Transplant Procedure	Immunosuppression and infection prophylaxis	Belatacept
2. Dose	i. _____		ii. _____
3. Therapy dates (if unknown, give best estimate)	i. Date of most recent islet transplantation ____ / ____ / ____ (dd/mm/yyyy)		ii. Introduction date ____ / ____ / ____ iii. Date of last dose ____ / ____ / ____ (dd/mm/yyyy)
4. Diagnosis for use	Type I Diabetes Mellitus		Islet Transplant/Immunosuppression
5. Event abated after use stopped or dose reduced?	i. <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Doesn't apply	ii. <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Doesn't apply	iii. <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Doesn't apply
6. Event reappeared after reintroduction?	i. <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Doesn't apply	ii. <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Doesn't apply	iii. <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Doesn't apply
7. Lot number	i. _____		ii. _____
8. Expiration Date (if known)	i. ____ / ____ / ____ (dd/mm/yyyy)		ii. ____ / ____ / ____ (dd/mm/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)

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.

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Mammogram

1) Date of mammogram: _____ / _____ / _____
(dd/mm/yyyy)

2) Mammogram interpreted as: (select one)

☐ Normal

☐ Abnormal; clinically significant

└─ a. Please specify abnormality:

☐ Abnormal; not clinically significant

└─ b. Please specify abnormality:

A. INCLUSION CRITERIA

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

- | | No | Yes | |
|----|-----------------------|-----------------------|---|
| 1. | <input type="radio"/> | <input type="radio"/> | Male and female subjects age 18 to 65 years of age. |
| 2. | <input type="radio"/> | <input type="radio"/> | Ability to provide written informed consent. |
| 3. | <input type="radio"/> | <input type="radio"/> | Mentally stable and able to comply with the procedures of the study protocol. |
| 4. | <input type="radio"/> | <input type="radio"/> | Clinical history compatible with type 1 diabetes with onset of disease at < 40 years of age and insulin-dependence for > 5 years at the time of enrollment, and a sum of subject age and insulin dependent diabetes duration of ≥ 28 . |
| 5. | <input type="radio"/> | <input type="radio"/> | Absent stimulated C-peptide (<0.3 ng/mL) in response to a mixed meal tolerance test (MMTT: 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. |
| 6. | <input type="radio"/> | <input type="radio"/> | 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. |
| 7. | <input type="radio"/> | <input type="radio"/> | At least one episode of severe hypoglycemia in the 12 months prior to study enrollment. |

A. INCLUSION CRITERIA (*continued*)**No Yes**

8. ☐ ☐ 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;
 - b. ☐ Marked glycemic lability characterized by wide swings in blood glucose despite optimal diabetes therapy and defined by an LI score greater than or equal to the 90th percentile ($433 \text{ mmol/L}^2/\text{hrwk}^{-1}$) during the screening period and within the last 6 months prior to randomization;
 - c. ☐ A composite of a Clarke score of 4 or more or a HYPO score greater than or equal to the 75th percentile (423) and an LI greater than or equal to the 75th percentile (329) during the screening period and within the last 6 months prior to randomization.

B. EXCLUSION CRITERIA

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

No Yes

1. ☐ ☐ BMI $>30 \text{ kg/m}^2$ or patient weight $\leq 50 \text{ kg}$.
2. ☐ ☐ Insulin requirement of $> 1.0 \text{ IU/kg/day}$ or $< 15 \text{ U/day}$.
3. ☐ ☐ HbA1c $> 10\%$.
4. ☐ ☐ Untreated proliferative diabetic retinopathy.
5. ☐ ☐ Blood Pressure: SBP $> 160 \text{ mmHg}$ or DBP $> 100 \text{ mmHg}$.
6. ☐ ☐ Measured glomerular filtration rate using iohexol of $<80 \text{ mL/min/1.73m}^2$ (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 $\leq 70 \text{ mL/min/1.73m}^2$ are excluded. The absolute (raw) GFR value will be used for subjects with body surface areas $> 1.73 \text{ m}^2$.
7. ☐ ☐ Presence or history of macroalbuminuria ($>300 \text{ mg/g creatinine}$).
8. ☐ ☐ Presence or history of panel-reactive anti-HLA antibodies above background by flow cytometry.
9. ☐ ☐ **For female participants:** 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 females of child bearing potential, two methods should be started 4 weeks prior to 1st dose of MMF.
For male participants: intent to procreate during the duration of the study or within 4 months after discontinuation or unwillingness to use effective measures of contraception.
ALL participants: must use two acceptable methods of contraception while taking MMF
Oral contraceptives, Norplant, Depo-Provera, and barrier devices with spermicide are acceptable contraceptive methods; condoms used alone are not acceptable.
10. ☐ ☐ Active infection including hepatitis B, hepatitis C, or HIV.
11. ☐ ☐ Negative screen for Epstein-Barr Virus (EBV) by IgG determination.

B. EXCLUSION CRITERIA *(continued)*

No Yes

12. ☐ ☐ Invasive aspergillus, histoplasmosis, and coccidioidomycosis infection within one year prior to study enrollment.
13. ☐ ☐ Any history of malignancy except for completely resected squamous or basal cell carcinoma of the skin.
14. ☐ ☐ Known active alcohol or substance abuse.
15. ☐ ☐ Baseline Hb below the lower limits of normal at the local laboratory; lymphopenia ($<1000/\mu\text{L}$), neutropenia ($<1500/\mu\text{L}$), or thrombocytopenia (platelets $<100,000/\mu\text{L}$). Participants with lymphopenia are allowed if the investigator determines there is no additional risk and obtains clearance from an independent hematologist.
16. ☐ ☐ A history of Factor V deficiency.
17. ☐ ☐ 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 . The use of Plavix is allowed only when portal vein access is obtained using a mini-laparotomy procedure at the time of islet transplant.
18. ☐ ☐ Severe co-existing cardiac disease, characterized by any one of these conditions:
- a) ☐ recent myocardial infarction (within past 6 months).
 - b) ☐ evidence of ischemia on functional cardiac exam within the last year.
 - c) ☐ left ventricular ejection fraction $<30\%$.
19. ☐ ☐ 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.
20. ☐ ☐ Symptomatic cholecystolithiasis.
21. ☐ ☐ Acute or chronic pancreatitis.
22. ☐ ☐ Symptomatic peptic ulcer disease.
23. ☐ ☐ Severe unremitting diarrhea, vomiting or other gastrointestinal disorders potentially interfering with the ability to absorb oral medications.
24. ☐ ☐ Hyperlipidemia despite medical therapy (fasting LDL cholesterol $> 130 \text{ mg/dL}$, treated or untreated; and/or fasting triglycerides $> 200 \text{ mg/dL}$).
25. ☐ ☐ Receiving treatment for a medical condition requiring chronic use of systemic steroids, except for the use of $\leq 5 \text{ mg}$ prednisone daily, or an equivalent dose of hydrocortisone, for physiological replacement.

B. EXCLUSION CRITERIA *(continued)*

- | | No | Yes | |
|-----|-----------------------|-----------------------|---|
| 26. | <input type="radio"/> | <input type="radio"/> | Treatment with any anti-diabetic medication other than insulin within 4 weeks of enrollment. |
| 27. | <input type="radio"/> | <input type="radio"/> | Use of any investigational agents within 4 weeks of enrollment. |
| 28. | <input type="radio"/> | <input type="radio"/> | Administration of live attenuated vaccine(s) within 2 months of enrollment. |
| 29. | <input type="radio"/> | <input type="radio"/> | Any medical condition that, in the opinion of the investigator, will interfere with the safe participation in the trial. |
| 30. | <input type="radio"/> | <input type="radio"/> | Treatment with any immunosuppressive regimen at the time of enrollment, or subjects with comorbidities for which treatment with such agents are likely during the trial. |
| 31. | <input type="radio"/> | <input type="radio"/> | A previous islet transplant. |
| 32. | <input type="radio"/> | <input type="radio"/> | 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. |
| 33. | <input type="radio"/> | <input type="radio"/> | Subject is a woman ≥ 35 years or is a woman of any age who has first degree relatives with a history of breast carcinoma, or who has other risk factors of breast carcinoma and has NOT had a screening mammogram performed within 6 months of enrollment. |
| 34. | <input type="radio"/> | <input type="radio"/> | Subject has a mammogram suspicious for malignancy and the possibility of malignancy cannot be reasonably excluded following additional clinical, laboratory, or other diagnostic evaluations. |
| 35. | <input type="radio"/> | <input type="radio"/> | Presence or history of active tuberculosis (TB). Subjects with laboratory evidence of active infection are excluded even in the absence of clinical evidence of active infection. |

B. EXCLUSION CRITERIA (*continued*)**No Yes**

36. ☐ ☐ Subject previously treated with belatacept.
37. ☐ ☐ Prisoner or subject who is compulsorily detained (involuntarily incarcerated) for treatment of either a psychiatric or physical (e.g., infectious disease) illness.
38. ☐ ☐ Known hypersensitivity to mycophenolate mofetil or any of the drug's components.
39. ☐ ☐ Rare hereditary deficiency of hypoxanthine-guanine phosphoribosyltransferase (HGPRT) such as Lesch-Nyhan and Kelly-Seegmiller syndrome.
40. ☐ ☐ Dietary restriction of phenylalanine.

A. INCLUSION CRITERIA

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| 7. | <input type="radio"/> | <input type="radio"/> | At least one episode of severe hypoglycemia in the 12 months prior to study enrollment. |

A. INCLUSION CRITERIA (*continued*)**No Yes**

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B. EXCLUSION CRITERIA *(continued)*

No Yes

12. ☐ ☐ Invasive aspergillus, histoplasmosis, and coccidioidomycosis infection within one year prior to study enrollment.
13. ☐ ☐ Any history of malignancy except for completely resected squamous or basal cell carcinoma of the skin.
14. ☐ ☐ Known active alcohol or substance abuse.
15. ☐ ☐ Baseline Hb below the lower limits of normal at the local laboratory; lymphopenia ($<1000/\mu\text{L}$), neutropenia ($<1500/\mu\text{L}$), or thrombocytopenia (platelets $<100,000/\mu\text{L}$). Participants with lymphopenia are allowed if the investigator determines there is no additional risk and obtains clearance from an independent hematologist.
16. ☐ ☐ A history of Factor V deficiency.
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B. EXCLUSION CRITERIA *(continued)*

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|-----|-----------------------|-----------------------|---|
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B. EXCLUSION CRITERIA (*continued*)

- | | No | Yes | |
|-----|-----------------------|-----------------------|---|
| 36. | <input type="radio"/> | <input type="radio"/> | Subject previously treated with belatacept. |
| 37. | <input type="radio"/> | <input type="radio"/> | Prisoner or subject who is compulsorily detained (involuntarily incarcerated) for treatment of either a psychiatric or physical (e.g., infectious disease) illness. |
| 38. | <input type="radio"/> | <input type="radio"/> | Known hypersensitivity to mycophenolate mofetil or any of the drug's components. |
| 39. | <input type="radio"/> | <input type="radio"/> | Rare hereditary deficiency of hypoxanthine-guanine phosphoribosyltransferase (HGPRT) such as Lesch-Nyhan and Kelly-Seegmiller syndrome. |
| 40. | <input type="radio"/> | <input type="radio"/> | Dietary restriction of phenylalanine. |

Subject ID _____ - _____ - _____

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

1. Date of Study Termination: ____/____/____ (dd/mm/yyyy)
2. Date of last follow up visit: ____/____/____ (dd/mm/yyyy)
3. Indicate the primary reason the subject will no longer be followed: (select one)
 - ☐ Subject completed study procedures per protocol
 - ☐ Subject withdrew consent from all future study activities, including follow-up
 - ☐ Lost to follow-up (Unable/unwilling to travel/moved from area/unable to locate)
 - ☐ Subject death
 - ☐ Complete the Adverse Event form
 - ☐ Subject develops a clinical AE, laboratory abnormality, or intercurrent illness which, in the opinion of the investigator, indicates that continued treatment with study therapy and further participation in the study (including vital status of the subject and islet graft) is not in the best interest of the subject
 - ☐ The development of belatacept is terminated by the manufacturer (BMS)
 - ☐ Subject becomes a prisoner or becomes involuntarily incarcerated for treatment of either a psychiatric or physical (e.g., infectious disease) illness
 - ☐ 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
 - ☐ Subject randomized but did not actually meet 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
 - ☐ Other
 - ☐ Please specify: _____

4. Comments (optional):