A. INVESTIGATIONAL AGENT

Drug	Date	Total Dose on this Date (mg)
○ Belatacept	_ _ / _ _ _ / _ _ _ _ (dd/mmm/yyyy)	

Add New Entry

B. INDUCTION MEDICATION

Drug	Date	Total Dose on this Date (mg)
○ Daclizumab ○ Basiliximab	_ _ / _ _ _ / _ _ _ _ (dd/mmm/yyyy)	

Add New Entry

Section A & B will be available for Induction only.

C. MAINTENANCE IMMUNOSUPPRESSION MEDICATIONS

Add New Entry

Drug	Total Dose (mg)/ Day	Start Date	Stop Date
○ Tacrolimus ○ Mycophenolate mofetil ○ Other		_ _ / _ _ _ / _ _ _ _ (dd/mmm/yyyy)	_ _ / _ _ _ / _ _ _ _ (dd/mmm/yyyy)

If Other, please complete Major Protocol Deviation form.

D. TROUGH LEVELS

Drug	Date of Draw	Trough Level
○ Tacrolimus	_ _ / _ _ _ / _ _ _ _ (dd/mmm/yyyy)	(ng/mL) ☐ Undetectable

Add New Entry

E. INFECTION PROPHYLAXIS MEDICATIONS

Add new Entry

Drug	Total Dose / Day	Start Date	Stop Date
○ TMP/SMX (SS=1 tab)* ○ Valganciclovir (mg) ○ Other		_ _ / _ _ _ / _ _ _ _ dd/mmm/yyyy	_ _ / _ _ _ / _ _ _ _ dd/mmm/yyyy

* single strength TMP = 80 mg SMX = 400 mg

F. ANTICOAGULANT MEDICATIONS

Add new Entry

Drug	Total Dose (mg) / Day	Start Date	Stop Date
○ Enoxaparin ○ Pentoxifylline ○ Aspirin		_ _ / _ _ _ / _ _ _ _ (dd/mmm/yyyy)	_ _ / _ _ _ / _ _ _ _ (dd/mmm/yyyy)

G. COMMENTS (optional)

Subject ID ____ ____ -____ ____ - ____ ____ ____

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) undectable 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)

BELATACEPT TROUGH LEVELS AND IMMUNOGENICITY SAMPLES

Subject ID ___ ___ -___ ___ - ___ ___ ___

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?

1. ○ No ○ Yes

- a. Date of draw __ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)
- b. Time of draw __ __:__ __ (0000-2359)
- c. Was Belatacept trough level aliquot obtained ? ○ yes ○ no
  If no for visits 04 -30 (Subs Tx days 4, 7, 75, and 365), please comment
- d. Was Immunogenicity sample aliquot obtained? ○ yes ○ 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

Reason:

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)

☐ 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)

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

B. SUSPECT MEDICATION(S)

	Suspect Medication 1	Suspect Medication 2	Suspect Medication 3
1. Name	i. Islet Transplantation (check all that may apply) ☐ Islet Product ☐ 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/mmm/yyyy)*		ii. Introduction date _ _ / _ _ _ / _ _ _ _ iii. Date of last dose _ _ / _ _ _ / _ _ _ _ *(dd/mmm/yyyy)*
4. Diagnosis for use	Type I Diabetes Mellitus	Islet Transplant/Immunosuppression	Islet Transplant/Immunosuppression
5. Event abated after use stopped or dose reduced?	i. O No O Yes O Doesn't apply	ii. O No O Yes O Doesn't apply	iii. O No O Yes O Doesn't apply
6. Event reappeared after reintroduction?	i. O No O Yes O Doesn't apply	ii. O No O Yes O Doesn't apply	iii. O No O Yes O Doesn't apply
7. Lot number	i.		ii.
8. Expiration Date (if known)	i. __ __ / __ __ __ / __ __ __ __ *(dd/mmm/yyyy)*		ii. __ __ / __ __ __ / __ __ __ __ *(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)

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 ____ ____ -____ ____ - ____ ____ ____

Mammogram

1) Date of mammogram: __ __ / __ __ __ / __ __ __ __
(dd/mmm/yyyy)

2) Mammogram interpreted as: (select one)

- ○ Normal
- ○ Abnormal; clinically significant
  - a. Please specify abnormality:
- ○ Abnormal: not clinically significant
  - b. Please specify abnormality:

CIT 04 EDMONTON AND EMORY RANDOMIZATION ELIGIBILITY

Subject ID ___ ___ -___ ___ - ___ ___ ___

A. INCLUSION CRITERIA

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

	No	Yes	
1.	○	○	Male and female subjects age 18 to 65 years of age.
2.	○	○	Ability to provide written informed consent.
3.	○	○	Mentally stable and able to comply with the procedures of the study protocol.
4.	○	○	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.	○	○	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.	○	○	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 the12 months prior to study enrollment.
7.	○	○	At least one episode of severe hypoglycemia in the12 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 $mmol/L^2/hr \cdot wk^{-1}$) 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 kg/m^2 or patient weight ≤ 50 kg.
2.	○	○	Insulin requirement of > 1.0 IU/kg/day or < 15 U/day.
3.	○	○	HbA1c > 10%.
4.	○	○	Untreated proliferative diabetic retinopathy.
5.	○	○	Blood Pressure: SBP > 160 mmHg or DBP > 100 mmHg.
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 m^2.
7.	○	○	Presence or history of macroalbuminuira (>300 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 accepatable 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/ 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 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 mg/dL, treated or untreated; and/or fasting triglycerides > 200mg/dL).
25.	○	○	Receiving treatment for a medical condition requiring chronic use of systemic steroids, except for the use of ≤ 5 mg prednisone daily, or an equivalent dose of hydorcortisone, for physiological replacement.

B. EXCLUSION CRITERIA *(continued)*

	No	Yes	
26.	○	○	Treatment with any anti-diabetic medication other than insulin within 4 weeks of enrollment.
27.	○	○	Use of any investigational agents within 4 weeks of enrollment.
28.	○	○	Administration of live attenuated vaccine(s) within 2 months of enrollment.
29.	○	○	Any medical condition that, in the opinion of the investigator, will interfere with the safe participation in the trial.
30.	○	○	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.	○	○	A previous islet transplant.
32.	○	○	A previous pancreas transplant, unless the graft failed within the first week due to thrombosis, followed by pancreatectomy and the transplant occured more than 6 months prior to enrollment.
33.	○	○	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.	○	○	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.	○	○	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.

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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

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

	No	Yes	
1.	○	○	Male and female subjects age 18 to 65 years of age.
2.	○	○	Ability to provide written informed consent.
3.	○	○	Mentally stable and able to comply with the procedures of the study protocol.
4.	○	○	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.	○	○	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.	○	○	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 the12 months prior to study enrollment.
7.	○	○	At least one episode of severe hypoglycemia in the12 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 mmol/L^2/hr·wk^{-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 kg/m^2 or patient weight ≤ 50 kg.
2.	○	○	Insulin requirement of > 1.0 IU/kg/day or < 15 U/day.
3.	○	○	HbA1c > 10%.
4.	○	○	Untreated proliferative diabetic retinopathy.
5.	○	○	Blood Pressure: SBP > 160 mmHg or DBP > 100 mmHg.
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 m^2.
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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 accepatable 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/ 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 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 islet 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 mg/dL, treated or untreated; and/or fasting triglycerides > 200mg/dL).
25.	○	○	Receiving treatment for a medical condition requiring chronic use of systemic steroids, except for the use of ≤ 5 mg prednisone daily, or an equivalent dose of hydorcortisone, for physiological replacement.

B. EXCLUSION CRITERIA *(continued)*

	No	Yes	
26.	○	○	Treatment with any anti-diabetic medication other than insulin within 4 weeks of enrollment.
27.	○	○	Use of any investigational agents within 4 weeks of enrollment.
28.	○	○	Administration of live attenuated vaccine(s) within 2 months of enrollment.
29.	○	○	Any medical condition that, in the opinion of the investigator, will interfere with the safe participation in the trial.
30.	○	○	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.	○	○	A previous islet transplant.
32.	○	○	A previous pancreas transplant, unless the graft failed within the first week due to thrombosis, followed by pancreatectomy and the transplant occured more than 6 months prior to enrollment.
33.	○	○	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.	○	○	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.	○	○	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.

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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.

STUDY TERMINATION

Subject ID ___ ___ - ___ ___- ___ ___ ___

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

1. Date of Study Termination: ___ ___/___ ___ ___ /___ ___ ___ ___ *(dd/mmm/yyyy)*

2. Date of last follow up visit: ___ ___/___ ___ ___ /___ ___ ___ ___ *(dd/mmm/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): _____