CIT-04

STUDY-SPECIFIC MANUAL OF PROCEDURES
(ACCOMPANIES PROTOCOL VERSION 7.0)

VERSION 7.0

JANUARY 18, 2012

CONFIDENTIAL

Table of Contents

List of Appendices

1 CIT-04 PROTOCOL COMMUNICATION PLAN

*See last page for Islet Manufacturing Communication Plan *

Who do I contact?

Site investigators should contact the NIH MM, Nancy Bridges, directly for:

- **urgent safety or eligibility issues not addressed by the protocol or questions requiring medical judgment**
- **publication questions** (publication notification forms, publication policy questions, etc.)

Site investigators or coordinators should contact the NIH PM, Allison Priore, directly for:

- review and approve any revision to your Informed Consents prior to IRB submission.
- NIH budget questions

Otherwise, the site investigator or coordinator should contact the DCC Protocol Coordinator for all CIT-04 protocol questions and concerns, including:

- Subject Recruitment: Screening process, enrollment, protocol eligibility, transplant wait list, blood sugar records, diabetologist certifications, central lab results, etc.
- Protocol Implementation: Study visits, prophylactic meds, prohibited meds, graft failures, study assessments, SAE reporting, deviations, logistics, source documentation, participant concerns, etc.
- Protocol Content: Statistics, endpoint analysis, rationale, background, etc.
- Data Management: Website access, electronic case report forms, queries, etc.
- Study drug: Shipments, storage, drug shipment requests, ancillary supplies, etc.
- Specimen Coordination: Kits, supplies, Immunotrak, specimen shipping and processing, timing of specimen collection, core labs, etc.
- Study Supplies: Glucometers, test strips, CGMS, etc.
- Study Documents: Brochures, protocol booklets, MOP, lab manual, participant ID cards, etc.
- Regulatory Documentation: IRB approvals, delegation log, expiring documents, documentation requirements, conflict of interest, financial disclosure, etc.
    - **All Health Authority communications must go through NIH.**

Contact information for your CIT-04 DCC Protocol Coordinator:

Cynthia Diltz
Phone: 319-353-4982
Fax: 319-353-3960
Cell/pager: 319-631-3935
Email: Cynthia-diltz@uiowa.edu

When to contact the NIH Project Manager directly:

- The NIH PM must review and approve any revision to your Informed Consents prior to IRB submission.
- NIH Budget questions should be sent to your NIH Project Manager.

Contact Info: **Email is the best way to communicate with the MMs*		
Thomas Eggerman MD, PhD*	(301) 594-8813	eggermant@extra.niddk.nih.gov
Nancy Bridges, MD*	(301) 451-4406	nbridges@niaid.nih.gov
Neal Green	(301) 594-8815	greenne@niddk.nih.gov
Allison Priore	(301) 560-4513	priorea@niaid.nih.gov
Natasha Watson	(301) 281-7003	natasha.watson@nih.gov

Assignments					
MM: Tom Eggerman PM: Neal Green		MM: Nancy Bridges PM: Allison Priore PM Back-up: Natasha Watson		MM: Nancy Bridges PM: Natasha Watson PM Back-up: Allison Priore	
Protocol:	Site Name	Protocol:	Site Name	Protocol:	Site Name
99, 02, 06	Miami	07	Miami	99, 03	Minnesota
99, 05, 06	Penn	07	Penn	99, 03	Northwestern
99, 02, 06	UIC	07	UIC	99, 03	UCSF
06	Edmonton	99, 04, 07	Edmonton		
06	Minnesota	07	Minnesota		
06	Northwestern	07	Northwestern		
06	UCSF	07	UCSF		
06	Emory	99, 04, 07	Emory		

Islet Laboratory Personnel:

Questions about islet potency and the islet manufacturing process should be addressed to the NIH Senior Regulatory Officer.

- Questions about completing Certificates of Analysis, Batch record completion, etc.
  - Submission and QA of manufacturing documents (COA, BR, etc.) are addressed separately in the manufacturing SOP.
- Clarifications to manufacturing process
- Questions about enzymes
- Manufacturing deviations

Contact information for the NIH Senior Regulatory Officer:
Julia Goldstein
Office: 301-451-3112
Fax: 301-402-2571
Email: jgoldstein@niaid.nih.gov

To place an enzyme order:

- Contact the Serva representative and copy Dixie Ecklund and Julia Goldstein.

2 CIT-04 PREGNANCY REPORTING

Investigator Instructions for reporting cases of pregnancy

Pregnancy testing must be performed throughout the study prior to the infusion with belatacept (LEA29Y) and the results of all pregnancy tests (positive or negative) recorded on the Pregnancy Test eCRF.

Women who are post-menopausal (defined as >/= 12 consecutive months of amenorrhea) and women who have had surgical sterilization are NOT Women of Child Bearing Potential (WOCBP) and do not need a pregnancy test.

No WOCBP with a positive test result can be given belatacept even if the site uses a pregnancy test that is more sensitive than the protocol required 25IU/L and the site believes the pregnancy test result is a false positive.

If following initiation of study treatment, it is subsequently discovered that a subject is pregnant or may have been pregnant at the time of investigational product exposure, including during at least 56 days after product administration, the investigational product will be permanently discontinued.

- As soon as the pregnancy is confirmed, notify PI.
- Complete SAE eCRF and submit to DCC within 24 hours.
- Complete Part 1 of the BMS Pregnancy Surveillance Form (*Appendix 1*) and either fax or include as supporting documents by attaching the document in the SAE eCRF within 24 hours. (Fax # 319-353-4231)
- Return Part II of the BMS Pregnancy Surveillance Form via fax (to DCC as above) after the outcome of the pregnancy is known, and, if applicable, when the infant is at least 8 weeks of age.
- Retain a completed copy of both Part I and Part II of the Pregnancy Surveillance Form with the subject's source doc or chart at the study site.
- An optional Pregnancy Worksheet (*Appendix 2*) has been created to compile additional details in maternal, fetal, and neonatal outcomes. The Worksheet is helpful for all pregnancies but is particularly helpful for those with problem outcomes. A hospital discharge summary or other narratives can be used instead of the Worksheet if sufficient information is provided.
- If pregnancy is applicable to female subjects receiving study drug
    - Do Not give Belatacept infusion
    - Complete CIT-04 Premature Discontinuation eCRF
    - Subject will transfer to the reduced follow-up SOE.
    - For subjects that discontinue Belatacept, collect additional immunogenicity samples at 4 weeks and 8 weeks post last dose.
- If pregnancy is applicable to the partner of male subjects receiving study drug
    - Complete the SAE and the BMS Pregnancy Surveillance forms as noted above
    - Male subjects do not need to discontinue study medication.

3 DOSING AND ADMINISTRATION OF BELATACEPT

Dosing Guidelines

Subjects will receive Belatacept 10mg/kg on days 0, 4, 14, 28, 56, and 84. A 10mg/kg dosing chart is provided in appendix 3. After day 84 subjects will receive a maintenance dose of 5 mg/kg every 4 weeks. A 5 mg/kg dosing chart is provided in appendix 4.

Administration Guidelines

- Prepare the patient for the belatacept infusion.
- Ensure the IV line is patent. A small gauge needle (21 or 23 gauge) is adequate to infuse belatacept solutions.
- An infusion pump may be used to administer the drug solution but is not required. A gravity infusion is acceptable.
- Explain the procedure to the patient.
- Ensure that informed consent has been documented as required by the institution/agency.

Check the solution by holding the bag up to the light. The solution should be clear. The solution cannot be used if it is cloudy or if it contains any sediment. Squeeze the bag and check for leaks. If there is anything wrong with the solution or the bag, inform the pharmacy.

The infusion solution should be administered at a constant rate over approximately 30 minute period (no more than ~ 3 mL/min or 200 mL/hour). Since no physical or biochemical compatibility studies have been conducted to evaluate co-administration of belatacept with other agents, belatacept should not be infused concomitantly in the same intravenous line as other agents. Once the infusion bag or bottle is empty, the IV line should be flushed thoroughly with approximately 20-30 mL of 5% Dextrose in Water or 0.9% Sodium Chloride solution to ensure that all active drug is delivered to the patient. Any unused portion of the infusion solution should not be stored for reuse and discarded.

4 ORDERING SUPPLIES FOR BELATACEPT INFUSIONS

All constitution and dilution of belatacept must be performed using silicone free disposable syringes and administered through a sterile, non-pyrogenic, low protein binding inline filter. These ancillary supplies (syringes and filters) for the belatacept infusion are supplied by BMS. An initial supply of syringes and filters will be sent with the first order of belatacept. Additional supplies may be ordered by contacting your CIT protocol coordinator.

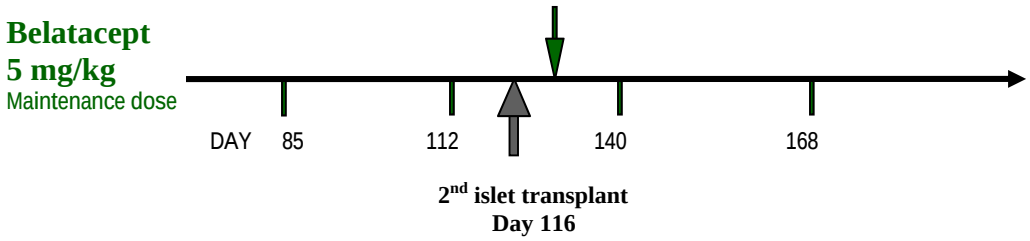
5 CLARIFICATION OF SUPPLEMENTARY DOSE OF BELATACEPT

If the subject requires a 2nd or 3rd islet transplant, in addition to the 5mg/kg maintenance dose, subjects will receive a single supplementary 10mg/kg dose of belatacept.

- If the second or third transplant is performed within 14 days after the last dose of belatacept, the supplementary dose will be administered approximately 14 days (within +/- 4 day visit window) after the last dose. In the example below the 2nd islet transplant occurs on day 116 and the last regularly scheduled maintenance dose of belatacept was given on day 112. Since the 2nd transplant occurs less than 14 days from the last maintenance dose the supplemental dose of 10mg/kg should be given on day 126 ± 4 days.
- The subject then resumes their 5 mg/kg maintenance dose schedule (e.g. maintenance dose on day 140, day 168, etc.)

CIT-04 Belatacept Dosing for 2nd/3rd islet transplants –
Example if < 14 days since last belatacept dose

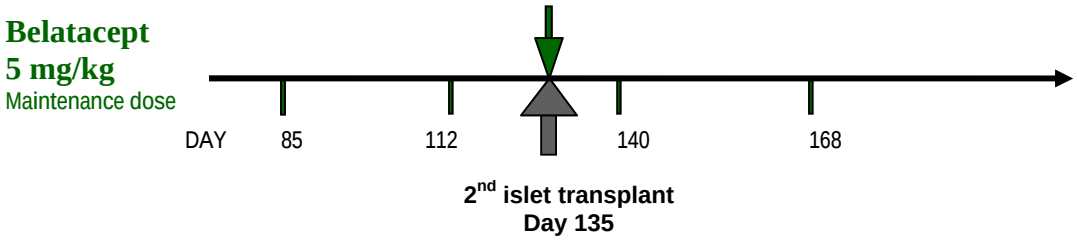
10 mg/kg supplemental dose day 126
(~14 days from last belatacept dose)



- If the second or third transplant is performed more than 14 days from the last dose of belatacept, the supplementary dose will be administered within 24 hours of the transplant.
  In the example below, the 2nd islet transplant occurs on day 135 and the last regularly scheduled maintenance dose of belatacept was given on day 112. Since the 2nd transplant occurs more than 14 days from the last maintenance dose the supplemental dose of 10mg/kg should be given within 24 hours of the transplant.
- The subject then resumes their maintenance dose schedule (e.g. maintenance dose on day 140, day 168, etc.)

CIT-04 Belatacept Dosing for 2nd/3rd islet transplants –
Example if > 14 days since last belatacept dose

10 mg/kg supplemental dose day 135
(within 24 hours of islet transplant)



NOTE: If the maintenance dose is scheduled to be given within four days of a supplemental dose, the maintenance dose should not be given. Subjects will resume maintenance dosing at their next scheduled visit.

6 UNDERSTANDING THE SCHEDULE OF EVENTS

The SOE for subjects randomized to CIT-04 can be confusing. The following section will explain how a subject follows the SOE depending on the number of transplants they have.

Belatacept infusions must be given every 4 weeks and the timing of the infusion is based on the first dose given on day 0 regardless of the timing of subsequent transplants.

6.1 Clarification for Appendix 4 (SOE for 1-Year additional Follow-ups)

When a subject has reached one year from their FINAL transplant, they will then begin to follow the SOE in CIT-04 Protocol Appendix 4 (Schedule of Events for 1-Year Additional Follow-up).
In the protocol, the 1-Year additional Follow-ups are entered in months with visit 59 listed as TBD (table 1).

Table 1: Appendix 4 -SOE for 1-Year Additional Follow-Up as written in CIT-04 Version 6.0

Visit Number	51	52	53	54	55	56	57	58	59	60	61	62	63	64
Time Point (months [M] relative to final islet transplant; years [Y] relative to intial transplant)	M13	M14	M15	M16	M17	M18	M19	M20	TBD	M21	M22	M23	M24	Y2

Since the subjects must come in to the clinic every 4 weeks (28 days) for the belatacept infusion, the subject will come for 13 visits in the additional year follow-up instead of 12, therefore the visit 59 TBD was added to accommodate the extra visit. However, referring to the time points as monthly is misleading since at some point during the year the subject will actually come in twice in 1 month and having a TBD visit is a moving target and confusing. Table 2 will clarify the time points for consistency and will be added to the next amendment.

Table 2: Clarification of the time points for Appendix 4- SOE for 1-Year Additional Follow-up

Clarification of time points for the 1-Year Additional Follow-up SOE

	Visit Number		51	52	53	54	55	56	57	58	59	60	61	62	63	64
Current	Time Point (months [M] relative to final islet transplant; years [Y]		M13	M14	M15	M16	M17	M18	M19	M20	TBD	M21	M22	M23	M24	Y2
Proposed	subject will follow the 1-Year additional SOE 28 days from last belatacept infusion and after subject reaches day 365 post final transplant	# of days from final transplant	D 393	D 421	D 449	D 477	D 505	D 533	D 561	D 589	D 617	D 645	D 673	D 701	D 730	730 days from 1st tx
		# of Wk since last belatacept infusion and Day 365 post final transplant	4 Wk	8 Wk	12 Wk	16 Wk	20 Wk	24 Wk	28 Wk	32 Wk	36 Wk	40 Wk	44 Wk	28 Wk	52 Wk	Y2

In table 2, the time points are also listed in days and weeks to reflect the number of days / number of weeks after the subject has completed their day 365 post final transplant visit. Calculation of the visits by # days works well if the subject has had only 1 transplant (see section 6.2). However if the subject

has received a subsequent transplant you must take into account the date of the last belatacept infusion after the subject has reached the 1 year post final transplant mark to calculate visit 51(see section 6.3).

For example, in table 1 visit number 51 is listed as M13 – 13 months from the final transplant. In table 2, visit number 51 can be thought of as Day 393 from the final transplant or 4 weeks after the subject's last dose of belatacept and has completed day 365 post final transplant. The TBD visit is removed and will always be visit 59.

6.2 How to Follow the SOEs for a subject who has only 1 transplant

Example – subject 04-XX-001 has a transplant June 2, 2009. Subject would follow Year 1 SOE (CIT-04 Protocol Appendix 1). Visit 21 (Wk52) is equal to the 1 year from initial transplant and would be scheduled for June 2, 2010. (*Note: Since the subject did not have a subsequent transplant the date of the initial transplant and the date of the final transplant are the same date*.)

Appendix 1 (Year 1 Schedule of Events)

Time points (specified in Days relative to **INITIAL** transplant)	Visit Number	Visit Windows (specified in days)	Equivalent Week/Month	Expected Date
0	03	N/A	N/A	2-Jun-09
3	03a	N/A	N/A	5-Jun-09
4	04	N/A	N/A	6-Jun-09
7	05	+/- 2	W1	9-Jun-09
14	06	+/- 2	W2	16-Jun-09
21	07	+/- 2	W3	23-Jun-09
28	08	+/- 3	W4	30-Jun-09
56	09	+/- 3	W8	28-Jul-09
75	10	+/- 5	N/A	16-Aug-09
84	11	+/- 3	W12	25-Aug-09
112	12	+/- 3	W16	22-Sep-09
140	13	+/- 3	W20	20-Oct-09
168	14	+/- 3	W24	17-Nov-09
196	15	+/- 5	W28	15-Dec-09
224	16	+/- 5	W32	12-Jan-10
252	17	+/- 5	W36	9-Feb-10
280	18	+/- 5	W40	9-Mar-10
308	19	+/- 5	W44	6-Apr-10
336	20	+/- 5	W48	4-May-10
365	21	+/- 5	W52 (Y1 Initial Tx)	2-Jun-10

Appendix 2 [Continuation of Appendix 1 Schedule of Events (Subjects with Subsequent Transplants)] and Appendix 3 (Subsequent Transplant Schedule of Events) are not needed.

Appendix 2 - NOT NEEDED
Continuation of Appendix 1 SOE
(Subjects with Subsequent Transplants)

Time points (specified in Days relative to **INITIAL** transplant)	Visit Number	Visit Windows (specified in days)	Equivalent Week/Month	Expected Date
~~392~~	~~22~~	~~+/- 5~~	~~W56~~	~~29-Jun-10~~
~~420~~	~~23~~	~~+/- 5~~	~~W60~~	~~27-Jul-10~~
~~448~~	~~24~~	~~+/- 5~~	~~W64~~	~~24-Aug-10~~
~~476~~	~~25~~	~~+/- 5~~	~~W68~~	~~21-Sep-10~~
~~504~~	~~26~~	~~+/- 5~~	~~W72~~	~~19-Oct-10~~
~~532~~	~~27~~	~~+/- 5~~	~~W76~~	~~16-Nov-10~~
~~560~~	~~28~~	~~+/- 5~~	~~W80~~	~~14-Dec-10~~
~~588~~	~~29~~	~~+/- 5~~	~~W84~~	~~11-Jan-11~~
~~616~~	~~30~~	~~+/- 5~~	~~W88~~	~~8-Feb-11~~

Appendix 3 - NOT NEEDED
Subsequent Transplant SOE

Time point (Relative to date of subsequnt transplant)	Visit Windows (specified in days)	Expected Date
Sub Tx Day 0	N/A	N/A
Sub Tx Day 3	N/A	N/A
Sub Tx Day 4	N/A	N/A
Sub Tx Day 7	+/-3	N/A
Sub Tx Day 75	+/-5	N/A
Sub Tx Day 365	+/-14	N/A

When the subject has completed visit 21, they would then follow Schedule of Events for 1-Year Additional Follow-Up (CIT-04 Protocol Appendix 4). Note in the case of only 1 transplant it is reasonable to use # of days for calculating the next visit since visit 51 will always be 393 days from initial transplant.
To help distinguish “day” or “weeks” in the 1 Year Additional Follow-up from “day” or “weeks” in the Initial year, AY will be added in appendix 4.

Appendix 4
SOE for 1 Year Additional Follow-Up
*AY = Additional Year

Time point (Equivalent Days post last bela dose after visit 'Day 365 post final transplant')	Visit Number	Visit Windows (specified in days)	Time point (Equivalent Weeks post last bela dose after visit 'Day 365 post final transplant')	Expected Date
D393 (AY)*	51	+/- 5	W4 (AY)*	30-Jun-10
D421 (AY)*	52	+/- 5	W8 (AY)*	28-Jul-10
D449 (AY)*	53	+/- 5	W12 (AY)*	25-Aug-10
D477 (AY)*	54	+/- 5	W16 (AY)*	22-Sep-10
D505 (AY)*	55	+/- 5	W20 (AY)*	20-Oct-10
D533 (AY)*	56	+/- 5	W24 (AY)*	17-Nov-10
D561 (AY)*	57	+/- 5	W28 (AY)*	15-Dec-10
D589 (AY)*	58	+/- 5	W32 (AY)*	12-Jan-11
D617 (AY)*	59	+/- 5	W36 (AY)*	9-Feb-11
D645 (AY)*	60	+/- 5	W40 (AY)*	9-Mar-11
D673 (AY)*	61	+/- 5	W44 (AY)*	6-Apr-11
D701 (AY)*	62	+/- 5	W48 (AY)*	4-May-11
D730 (AY)*	63	+/- 5	W52 (AY)*	1-Jun-11
Y2	64	+/- 30	W104 (Y2 Intial Tx)	2-Jun-11

Since Subject had only 1 transplant the date of intial transplant and date of final transplant are the same. Subject would continue to come in every 28 days until they reach 2 years.

NOTE- The Y2 visit is same as visit 63 (W52 from final transplant)

6.3 How to Follow the SOEs for a subject who has only a subsequent transplant

Example – subject 04-XX-002 had a transplant June 2, 2009. Subject begins to follow Year 1 SOE (CIT-04 Protocol Appendix 1). On December 23, 2009 the subject undergoes a 2nd transplant. To capture endpoint assessments for subsequent transplants, the subject must also follow the "Subsequent Transplant Schedule of Events" (CIT-04 Protocol Appendix 3). If any of these (subsequent transplant) visits falls within the acceptable window for a (first transplant) follow-up visit, the assessments from the two visits can be combined into a single visit. Visit 21 (Wk52) represents the 1 year from initial transplant visit and would be scheduled for June 2, 2010.

Time points for Appendix 1 and 2 are calculated from the date of the INITIAL transplant

Appendix 1 (Year 1 Schedule of Events)

Time points (specified in Days relative to **INITIAL** transplant)	Visit Number	Visit Windows (specified in days)	Equivalent Week/Month	Expected Date
0	03	N/A	N/A	2-Jun-09
3	03a	N/A	N/A	5-Jun-09
4	04	N/A	N/A	6-Jun-09
7	05	+/- 2	W1	9-Jun-09
14	06	+/- 2	W2	16-Jun-09
21	07	+/- 2	W3	23-Jun-09
28	08	+/- 3	W4	30-Jun-09
56	09	+/- 3	W8	28-Jul-09
75	10	+/- 5	N/A	16-Aug-09
84	11	+/- 3	W12	25-Aug-09
112	12	+/- 3	W16	22-Sep-09
140	13	+/- 3	W20	20-Oct-09
168	14	+/- 3	W24	17-Nov-09
196	15	+/- 5	W28	15-Dec-09
224	16	+/- 5	W32	12-Jan-10
252	17	+/- 5	W36	9-Feb-10
280	18	+/- 5	W40	9-Mar-10
308	19	+/- 5	W44	6-Apr-10
336	20	+/- 5	W48	4-May-10
365	21	+/- 5	W52 (Y1 Initial Tx)	2-Jun-10

Appendix 3
If any visit falls within an acceptable window on another SOE, the assessments may be added to that visit so that a separate visit does not need to occur.

Time Points for Appendix 3 "Subsequent Transplant SOE" are calculated from the date of the Sub Tx

Time point	Window	Expected Date
Sub Tx Day 0	N/A	23-Dec-09
Sub Tx Day 3	N/A	26-Dec-09
Sub Tx Day 4	N/A	27-Dec-09
Sub Tx Day 7	+/-3	30-Dec-09
Sub Tx Day 75	+/-5	8-Mar-10

To allow for one year of follow-up post-final transplant, the subject must be followed through December 23, 2010 before they begin the "1-Year Additional Year Follow-Up". To accomplish this, after the subject completes Visit 21 they would then follow the "Continuation of Appendix 1 Schedule of Events" (CIT-04 Protocol Appendix 2) until s/he reaches the visit one year after his/her final transplant (Sub Tx Day 365 or 23/Dec/2010). In this example, Visit 28 is scheduled for 14/Dec/2009 and Sub Tx Day 365 is scheduled for 23/Dec/2010, these visits can be combined since they fall within the acceptable window for both visits. Notice that visits 29 and 30 will not be required and are therefore crossed out.

Appendix 2
(Continuation of Appendix 1 SOE for Subjects with Subsequent Transplants)

Time points (specified in Days relative to **INITIAL** transplant)	Visit Number	Visit Windows (specified in days)	Equivalent Week/Month	Expected Date
392	22	+/- 5	W56	29-Jun-10
420	23	+/- 5	W60	27-Jul-10
448	24	+/- 5	W64	24-Aug-10
476	25	+/- 5	W68	21-Sep-10
504	26	+/- 5	W72	19-Oct-10
532	27	+/- 5	W76	16-Nov-10
560	28	+/- 5	W80	14-Dec-10
~~588~~	~~29~~	~~+/- 5~~	~~W84~~	~~11-Jan-11~~
~~616~~	~~30~~	~~+/- 5~~	~~W88~~	~~8-Feb-11~~

Appendix 3 (Cont)

Time point	Window	Expected Date
Sub Tx Day 365	+/-14	23-Dec-10

At that time, s/he would begin to follow the "Schedule of Events for 1-year Additional Follow-up from FINAL Transplant" (CIT-04 Protocol Appendix 4). Following Appendix 4 for subjects who have had subsequent transplants is not as straight forward as it was in section 6.2 when the subject only had 1 transplant. There are a few things to point out when working with appendix 4 for subjects who have had subsequent transplants.

Appendix 4
SOE for 1-Year Additional Follow-Up
*AY = Additional Year

Time point (Equivalent Days post last bela dose after visit 'Day 365 post final transplant')	Visit Number	Visit Windows (specified in days)	Time point (Equivalent Weeks post last bela dose after visit 'Day 365 post final transplant')	Expected Date
D393 (AY)*	51	+/- 5	W4 (AY)*	11-Jan-11
D421 (AY)*	52	+/- 5	W8 (AY)*	8-Feb-11
D449 (AY)*	53	+/- 5	W12 (AY)*	8-Mar-11
D477 (AY)*	54	+/- 5	W16 (AY)*	5-Apr-11
D505 (AY)*	55	+/- 5	W20 (AY)*	3-May-11
D533 (AY)*	56	+/- 5	W24 (AY)*	31-May-11
D561 (AY)*	57	+/- 5	W28 (AY)*	28-Jun-11
D589 (AY)*	58	+/- 5	W32 (AY)*	26-Jul-11
D617 (AY)*	59	+/- 5	W36 (AY)*	23-Aug-11
D645 (AY)*	60	+/- 5	W40 (AY)*	20-Sep-11
D673 (AY)*	61	+/- 5	W44 (AY)*	18-Oct-11
D701 (AY)*	62	+/- 5	W48 (AY)*	15-Nov-11
D730 (AY)*	63	+/- 5	W52 (AY)*	13-Dec-11

Visit 64 (Y2)	+/-30	2-Jun-11

Key Points to Consider when subjects are following Appendix 4 and the subject has had a Subsequent transplant(s):

- Because the subject must continue to come for belatacept infusions every 28 days you will notice that visit 51 is scheduled 28 days from the last belatacept infusion (14Dec2010) and not 28 days from 1 year post final transplant (23Dec2010).
- Visits under appendix 2 stop when the subject has completed Sub Tx Day 365. Visit 51 replaces the next available visit time point. In this scenario the subject combined visit Sub Tx Day 365 with visit 28 therefore visit 51 replaces visit 29.
- In Appendix 4, AY is added to the "Day" or "Week" to give the visit a unique identifier. AY stands for Additional Year. For example, the subject will complete Week 4 after the initial transplant (visit 8 on appendix 1) and the subject will complete week 4 in the additional year follow-up (visit 51 on appendix 4). To help distinguish between the 2 visits, AY will be added if the visit is in the additional year follow-up.
- In Appendix 4, you will notice a Visit 63 (Month 24/Day 730/Wk 52 from the final transplant) and a Visit 64 (Y2 – 2 years from initial transplant). If the subject has had a subsequent transplant, these visits will not fall on the same day. In the example, visit 63 would be scheduled for December 23, 2011, and visit 64 would be scheduled for June 2, 2011

7 CHECKLIST FOR INCLUSION/EXCLUSION CRITERIA FOR EDMONTON AND EMORY

Subjects at Edmonton and Emory must follow the Inclusion / Exclusion criteria based on the CIT04 protocol. A checklist to assist in subjects' eligibility based on CIT -04 inclusion/exclusion criteria is included in *Appendix 5*. Study coordinators are not required to complete or file a copy of this checklist. However, completing and filing the checklist with an investigator's signature at the bottom is a simple way to document that a subject meets all inclusion/exclusion criteria. Study monitors will seek additional source documentation of items in the checklist that are highlighted in grey. The investigator's signature on the checklist can serve to document that s/he has assessed the criteria that are not highlighted and believes that the subject meets the criteria.

Appendix 1 BMS Pregnancy Surveillance Form

Bristol-Myers Squibb Company
Pharmaceutical Research Institute

CARES FILE #	DOCUMENT LINK #	INVESTIGATOR NAME

PROTOCOL NUMBER | SITE NUMBER : | SUBJECT NUMBER : | SUBJECT INITIALS :

INSTITUTION | ADDRESS | COUNTRY

DATE OF BIRTH (DD-MMM-YY): | RACE *(circle one)*: 1 = White 2 = Black 3 = Asian 98 = Other _____

PREGNANCY SURVEILLANCE FORM - PART I

This form **(Part I)** must be completed and forwarded to Bristol-Myers Squibb (BMS) as soon as the investigator is notified that a pregnancy has occurred in a subject/patient enrolled in a BMS clinical trial. It must be completed on all pregnant subjects/patients irrespective of treatment (active drug, comparator or placebo). **Part II** should be completed when the pregnancy outcome is known. **NOTE:** If additional space is needed for an item, record this information on a **Pregnancy Surveillance Supplemental Information** form.

- **Method(s) of Contraception During Study Participation** (Methods and dates should be obtained from the study subject when pregnancy is identified and not taken only from the case report form. Include all methods used during study participation.)

Dates (DD/MMM/YY)

1 = Abstinence ____ to ____

2 = Oral Contraceptive Specify drug: _____ ____ to ____

98 = Other Specify Method: _____ ____ to ____

98 = Other Specify Method: _____ ____ to ____

Was the patient taking investigational product at the time of conception? (circle one) 1 = Yes 0 = No 4 = Unknown

- **Pregnancy Status**

Onset Date of Last Menstrual Period: ____ (DD MMM YY)

Date of Last Negative Pregnancy Test: ____ (DD MMM YY)

Date Pregnancy Confirmed: ____ (DD MMM YY)

Test Method: ☐ serum ☐ urine

β-HCG results (if known):_____ IU/L

Estimated Gestational Age When Pregnancy Diagnosed: _____ weeks

Prenatal testing performed: (circle one) 1 = Yes 0 = No 4 = Unknown If yes, specify test(s):

☐ **Ultrasound** Date ____ ☐ **Amniocentesis** Date ____ **Other** ☐ *(specify):* _____ Date ____

Findings: _____

Gravidity _____ Parity _____ Number of Living Children: _____

Previous Children with Congenital Abnormalities: (circle one) 1 = Yes 0 = No If yes, describe _____

Previous Spontaneous Abortions or Stillbirths: (circle one) 1 = Yes 0 = No If yes, specify: _____

Additional relevant information or comments:

INVESTIGATIONAL PRODUCT	DATE STARTED (DD MMM YY)	DATE STOPPED (DD MMM YY)	TOTAL DAILY DOSE (If known)	UNITS	ROUTE OF ADM. (eg. IM; PO)	NO. OF COURSES (if applicable)

CONCOMITANT MEDICATIONS	DATE STARTED (DD MMM YY)	DATE STOPPED (DD MMM YY)	OTHER LABORATORY TEST(S) RELEVANT TO THIS PREGNANCY (e.g. hemoglobin, glucose, etc.)	DATE OF TEST (DD MMM YY)	RESULTS (units) VALUE	RESULTS (units) NORMAL RANGE

RELEVANT MATERNAL MEDICAL HISTORY/ADDITIONAL COMMENTS (if any): _____

Prepared by (Signature) : _____ Date : (DD MMM YY) ____ Investigator (Signature) : _____ Date : (DD MMM YY) ____

March 16, 2005 GD SOP Form 11.01-1 Page 1 of 3 *ORIGINAL & CANARY COPY - BRISTOL-MYERS SQUIBB; PINK COPY - INVESTIGATOR*

Bristol-Myers Squibb Company
Pharmaceutical Research Institute

CARES FILE #	DOCUMENT LINK #	INVESTIGATOR NAME

PROTOCOL NUMBER | SITE NUMBER : | SUBJECT NUMBER : | SUBJECT INITIALS :

INSTITUTION | ADDRESS | COUNTRY

PREGNANCY SURVEILLANCE FORM - PART II

This form **(Part II)** must be completed and forwarded to BMS when the pregnancy outcome is known. Circle all items that apply. If **Part I** has not already been sent to BMS for this subject, it should also be completed and forwarded to BMS.

- **Pregnancy Outcome (circle one)**

  1 = Outcome known (Complete below)

  4 = Subject lost to follow-up; pregnancy outcome unknown (Document attempts to locate subject).

  _____

- **Investigational Product Status**

  0 = Investigational product discontinued on: ⌊__⌋⌊__⌋⌊__⌋⌊__⌋⌊__⌋⌊__⌋ (DD MMM YY)

  1 = Investigational product continued during this pregnancy:

  Dates ⌊__⌋⌊__⌋⌊__⌋⌊__⌋⌊__⌋⌊__⌋ (DD MMM YY) to ⌊__⌋⌊__⌋⌊__⌋⌊__⌋⌊__⌋⌊__⌋ (DD MMM YY)

- **Maternal Outcome**

  Did obstetrical complications or maternal medical conditions occur during this pregnancy?

  1 = Yes 2 = No 4 = Unknown

  If yes, specify: _____

  Date Pregnancy Ended: ⌊__⌋⌊__⌋⌊__⌋⌊__⌋⌊__⌋⌊__⌋ (DD MMM YY)

  Relationship of medical/obstetrical complications to investigational product:

  1 = Certain
  2 = Probable
  3 = Possible
  6 = Not Likely
  4 = Unrelated (If cause known, specify): _____

- **Fetal/Neonatal Outcome**

  1 = Normal, healthy infant

	Birth Defect Noted?		
5 = Live infant with a medical problem	1 = Yes	0 = No	4 = Unknown
3 = Abortion, spontaneous	1 = Yes	0 = No	4 = Unknown
4 = Abortion, induced	1 = Yes	0 = No	4 = Unknown
2 = Stillbirth	1 = Yes	0 = No	4 = Unknown

Relationship of outcome to investigational product:

1 = Certain
2 = Probable
3 = Possible
6 = Not Likely
4 = Unrelated (If cause known, specify): _____

Estimated gestational age (if known) when pregnancy ended:_____ weeks

Sex: 1 = Male 2 = Female **Birth weight:** _____ lbs/grams

If any birth defects were noted or neonatal problems occurred (eg, prematurity, jaundice, respiratory distress), please describe: _____

Additional factors that may have had an impact on the outcome of this pregnancy (eg, drugs, infections, medical, economic, occupational, other exposures or conditions, family history): _____

NOTE: Additional information on a pregnancy outcome may be requested by BMS particularly for pregnancies with medical/obstetrical complications or adverse fetal/neonatal outcomes or birth defects.

Prepared by (Signature) : _____ Date : ⌊__⌋⌊__⌋⌊__⌋⌊__⌋⌊__⌋⌊__⌋ (DD MMM YY)

Investigator (Signature) : _____ Date : ⌊__⌋⌊__⌋⌊__⌋⌊__⌋⌊__⌋⌊__⌋ (DD MMM YY)

March 16, 2005 GD SOP Form 11.01-1 Page 2 of 3

ORIGINAL & WHITE COPY - BRISTOL-MYERS SQUIBB; PINK COPY - INVESTIGATOR

Bristol-Myers Squibb Company
Pharmaceutical Research Institute

CARES FILE #	DOCUMENT LINK #	INVESTIGATOR NAME

PROTOCOL NUMBER | SITE NUMBER : | SUBJECT NUMBER : | SUBJECT INITIALS :

INSTITUTION	ADDRESS	COUNTRY

PREGNANCY SURVEILLANCE SUPPLEMENTAL INFORMATION

If additional space is needed to describe an item listed on **Parts I or II of the Pregnancy Surveillance Form,** it may be recorded below. Examples of items which may need further description include additonal methods of contraception (and dates), prenatal testing results, additional investigational products, laboratory test results, concomitant medications and any other additional history or comments.

Prepared by (Signature) : _____ Date : DD MMM YY

Investigator (Signature) : _____ Date : DD MMM YY

March 16, 2005 GD SOP Form 11.01-1 Page 3 of 3

ORIGINAL & WHITE COPY - BRISTOL-MYERS SQUIBB; PINK COPY - INVESTIGATOR

Appendix 2 BMS Pregnancy Worksheet

Bristol-Myers Squibb Company
Pharmaceutical Research Institute
Disease Management Area

PROTOCOL | SITE NUMBER : | SUBJECT NUMBER : | SUBJECT INITIALS :

INSTITUTION | ADDRESS | COUNTRY

DATE OF BIRTH (DD-MMM-YY): | RACE *(circle one)*: 1 = White 2 = Black 3 = Asian 98 = Other _____

PREGNANCY WORKSHEET

This worksheet can be used to collect additional maternal and fetal/neonatal information on a pregnancy occurring in a BMS Clinical Research Trial, particularly one associated with complications and/or birth defects.

- **Investigational Product:** _____ **Treatment Indication:** _____

Dates of Administration: DD MMM YY to DD MMM YY

PREGNANCY COURSE

- **Smoking during this Pregnancy** (circle one) 1 = Yes 0 = No
If yes, number of cigarettes / day _____
- **Average Alcohol Intake during this Pregnancy:** (circle one) 0 = None 1 = < 1 drink/day
2 = 1-2 drinks/day 3 = ≥ 3 drinks/day
- **Infections/Medical Conditions during this Pregnancy**
Did the patient have any of the following infections or medical conditions immediately prior to or during this pregnancy?
(circle one) 1 = Yes 0 = No If yes, record below.

Infection/Condition	Trimester of Occurrence (Check all that apply)				If any infections or medical conditions occurred prior to or during this pregnancy, please provide details. Include dates of occurrence, treatment, antibody titers, culture results, etc., if applicable.
	Prior to	1	2	3	
Diabetes Mellitus					
High Blood Pressure					
Epilepsy/Seizures					
Asthma					
Kidney Disease (specify)					
Liver Disease (specify)					
CMV (cytomegalovirus)					
Hepatitis B					
Toxoplasmosis					
Rubella					
Sexually-transmitted diseases (specify)					
Parvovirus					
Varicella					
Herpes simplex virus					
Other (specify)					
Other (specify)					

March 16, 2005 GD SOP Form 11.01-2 Page 1 of 4

Appendix 3 Dosing Chart for Belataecpt - 10mg/kg (100mg vial)

Dosing Chart for Belatacept 10 mg/kg (100mg vial)

Weight (kg)	Total Dose (mg)	Volume (mL)	# Vials Required
40	400	16.00	4
41	410	16.40	5
42	420	16.80	5
43	430	17.20	5
44	440	17.60	5
45	450	18.00	5
46	460	18.40	5
47	470	18.80	5
48	480	19.20	5
49	490	19.60	5
50	500	20.00	5
51	510	20.40	6
52	520	20.80	6
53	530	21.20	6
54	540	21.60	6
55	550	22.00	6
56	560	22.40	6
57	570	22.80	6
58	580	23.20	6
59	590	23.60	6
60	600	24.00	6
61	610	24.40	6
62	620	24.80	7
63	630	25.20	7
64	640	25.60	7
65	650	26.00	7
66	660	26.40	7
67	670	26.80	7
68	680	27.20	7
69	690	27.60	7

Weight (kg)	Total Dose (mg)	Volume (mL)	# Vials Required
70	700	28.00	7
71	710	28.40	7
72	720	28.80	8
73	730	29.20	8
74	740	29.60	8
75	750	30.00	8
76	760	30.40	8
77	770	30.80	8
78	780	31.20	8
79	790	31.60	8
80	800	32.00	8
81	810	32.40	8
82	820	32.80	9
83	830	33.20	9
84	840	33.60	9
85	850	34.00	9
86	860	34.40	9
87	870	34.80	9
88	880	35.20	9
89	890	35.60	9
90	900	36.00	9
91	910	36.40	9
92	920	36.80	10
93	930	37.20	10
94	940	37.60	10
95	950	38.00	10
96	960	38.40	10
97	970	38.80	10
98	980	39.20	10
99	990	39.60	10

Appendix 4 Dosing Chart for Belatacept - 5mg/kg (100mg vial)

Dosing Chart for Belatacept 5 mg/kg

Weight (kg)	Total Dose (mg)	Volume (mL)	# 100 mg Vials Required	# 250 mg Vials Required
40	200	8.00	2	1
41	205	8.20	3	1
42	210	8.40	3	1
43	215	8.60	3	1
44	220	8.80	3	1
45	225	9.00	3	1
46	230	9.20	3	1
47	235	9.40	3	1
48	240	9.60	3	1
49	245	9.80	3	1
50	250	10.00	3	1
51	255	10.20	3	2
52	260	10.40	3	2
53	265	10.60	3	2
54	270	10.80	3	2
55	275	11.00	3	2
56	280	11.20	3	2
57	285	11.40	3	2
58	290	11.60	3	2
59	295	11.80	3	2
60	300	12.00	3	2
61	305	12.20	4	2
62	310	12.40	4	2
63	315	12.60	4	2
64	320	12.80	4	2
65	325	13.00	4	2
66	330	13.20	4	2
67	335	13.40	4	2
68	340	13.60	4	2
69	345	13.80	4	2

Weight (kg)	Total Dose (mg)	Volume (mL)	# 100 mg Vials Required	# 250 mg Vials Required
70	350	14.00	4	2
71	355	14.20	4	2
72	360	14.40	4	2
73	365	14.60	4	2
74	370	14.80	4	2
75	375	15.00	4	2
76	380	15.20	4	2
77	385	15.40	4	2
78	390	15.60	4	2
79	395	15.80	4	2
80	400	16.00	4	2
81	405	16.20	5	2
82	410	16.40	5	2
83	415	16.60	5	2
84	420	16.80	5	2
85	425	17.00	5	2
86	430	17.20	5	2
87	435	17.40	5	2
88	440	17.60	5	2
89	445	17.80	5	2
90	450	18.00	5	2
91	455	18.20	5	2
92	460	18.40	5	2
93	465	18.60	5	2
94	470	18.80	5	2
95	475	19.00	5	2
96	480	19.20	5	2
97	485	19.40	5	2
98	490	19.60	5	2
99	495	19.80	5	2

Appendix 5 Edmonton and Emory Inclusion/Exclusion Criteria Checklist

CIT Islet-Alone Inclusion/Exclusion Criteria Checklist for Edmonton and Emory

Subject ID: __ __ - __ __ - __ __ __

The greyed-out criteria listed below require additional source documentation.

INCLUSION CRITERIA		
Criterion Met?	**Criterion**	**Location in source documents**
No ☐ Yes ☐	Male and female patients age 18 to 65 years of age.	Medical Record
No ☐ Yes ☐	Ability to provide written informed consent.	
No ☐ Yes ☐	Mentally stable and able to comply with the procedures of the study protocol.	
No ☐ Yes ☐	Clinical history compatible with T1D 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.	Endocrinologist questionnaire
No ☐ Yes ☐	Absent stimulated c-peptide (<0.3ng/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.	Central lab results
No ☐ Yes ☐	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.	Endocrinologist questionnaire
No ☐ Yes ☐	At least one episode of severe hypoglycemia in the 12 months prior to study enrollment.	Endocrinologist questionnaire
No ☐ Yes ☐	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; OR 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 $mmol/L^2/h \cdot wk^{-1}$) during the screening period and within the last 6 months prior to randomization; OR 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 of equal to the 75th percentile (329) during the screening period and within the last 6 months prior to randomization.	Screenshots of metabolic and Clarke score calculations

Subject ID: __ __ - __ __ - __ __ __

EXCLUSION CRITERIA		
Criterion Met?	**Criterion**	**Location in source documents**
No ☐ Yes ☐	Body mass index (BMI) >30 kg/m^2 or patient weight ≤50kg.	Medical record
No ☐ Yes ☐	Insulin requirement of >1.0 IU/kg/day or <15 U/day.	Medical record
No ☐ Yes ☐	HbA1c >10%.	Central lab results
No ☐ Yes ☐	Untreated proliferative diabetic retinopathy.	Medical record
No ☐ Yes ☐	Blood Pressure: SBP >160 mmHg or DBP >100 mmHg.	Medical record
No ☐ Yes ☐	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.	Central lab results
No ☐ Yes ☐	Presence or history of macroalbuminuria (>300mg/g creatinine).	Central lab results
No ☐ Yes ☐	Presence or history of panel-reactive anti-HLA antibodies above background by flow cytometry.	Central lab results
No ☐ Yes ☐	For female subjects: Positive serum 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. Subjects must use two acceptable methods of contraception while taking mycophenolate mofetil (MMF). For females of child bearing potential, the two methods should be started 4 weeks prior to first dose of MMF. Oral contraceptives, Norplant®, Depo-Provera®, and barrier devices with spermicide are acceptable contraceptive methods; condoms used alone are not acceptable.	
No ☐ Yes ☐	Active infection including hepatitis B, hepatitis C, or HIV.	Medical record
No ☐ Yes ☐	Negative screen for Epstein-Barr Virus (EBV) by IgG determination.	Medical record
No ☐ Yes ☐	Invasive aspergillus, histoplasmosis, and coccidoidomycosis infection within one year prior to study enrollment.	

Subject ID: __ __ - __ __ - __ __ __

EXCLUSION CRITERIA		
Criterion Met?	**Criterion**	**Location in source documents**
No ☐ Yes ☐	Any history of malignancy except for completely resected squamous or basal cell carcinoma of the skin.	
No ☐ Yes ☐	Known active alcohol or substance abuse.	
No ☐ Yes ☐	Baseline Hb below the lower limits of normal at the local laboratory; lymphopenia (<1,000/µL), neutropenia (<1,500/µL), or thrombocytopenia (platelets <100,000/µL). Participants with lymphopenia are allowed if the investigator determines there is no additional risk and obtains clearance from an independent hematologist.	Medical record
No ☐ Yes ☐	A history of Factor V deficiency.	
No ☐ Yes ☐	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 international normalized ratio (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.	
No ☐ Yes ☐	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%.	Medical record
No ☐ Yes ☐	Persistent elevation of liver function tests at the time of study entry. Persistent serum glutamic-oxaloacetic transaminase (SGOT [AST]), serum glutamate pyruvate transaminase (SGPT [ALT]), Alk Phos or total bilirubin, with values >1.5 times normal upper limits will exclude a patient.	Medical record
No ☐ Yes ☐	Symptomatic cholecystolithiasis.	
No ☐ Yes ☐	Acute or chronic pancreatitis.	
No ☐ Yes ☐	Symptomatic peptic ulcer disease.	
No ☐ Yes ☐	Severe unremitting diarrhea, vomiting or other gastrointestinal disorders potentially interfering with the ability to absorb oral medications.	
No ☐ Yes ☐	Hyperlipidemia despite medical therapy (fasting low-density lipoprotein [LDL] cholesterol >130 mg/dL, treated or untreated; and/or fasting triglycerides >200 mg/dL).	Medical record

Subject ID: __ __ - __ __ - __ __ __

EXCLUSION CRITERIA		
Criterion Met?	**Criterion**	**Location in source documents**
No ☐ Yes ☐	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 hydrocortisone, for physiological replacement.	
No ☐ Yes ☐	Treatment with any anti-diabetic medication other than insulin within 4 weeks of enrollment.	
No ☐ Yes ☐	Use of any investigational agents within 4 weeks of enrollment.	
No ☐ Yes ☐	Administration of live attenuated vaccine(s) within 2 months of enrollment.	
No ☐ Yes ☐	Any medical condition that, in the opinion of the investigator, will interfere with safe participation in the trial.	
No ☐ Yes ☐	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.	
No ☐ Yes ☐	A previous islet transplant.	
No ☐ Yes ☐	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.	
No ☐ Yes ☐	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.	
No ☐ Yes ☐	Subject has a mammogram suspicious for malignancy and the possibility of malignancy cannot be reasonable excluded following additional clinical, laboratory, or other diagnostic evaluations.	
No ☐ Yes ☐	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.	Medical record
No ☐ Yes ☐	Subjects previously treated with belatacept	
No ☐ Yes ☐	Prisoners or subjects who are compulsorily detained (involuntarily incarcerated) for treatment of either a psychiatric or physical (e.g., infectious disease) illness.	
No ☐ Yes ☐	Known hypersensitivity to mycophenolate mofetil or any of the drug's components	
No ☐ Yes ☐	Rare hereditary deficiency of hypoxanthine-guanine phophoribosyltransferase (HGPRT) such as Lesch-Nyhan and Kelly-Seegmiller syndrome	
No ☐ Yes ☐	Dietary restriction of phenylalanine	

Comments:

I have reviewed this checklist and confirm that all inclusion/exclusion criteria have been met.

Signature of PI or designee (listed on 1572) Date