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.)

5. **No** **Yes**
   ○ ○ 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 ____ ____ -____ ____ - ____ ____ ____

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

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

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

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

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

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

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

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

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

	No	Yes	
12.	○	○	Was a study-related islet transplant procedure ever initiated for this subject?

a. Relationship to islet transplantation
- ○ Definite
- ○ Probable
- ○ Possible
- ○ Unlikely
- ○ Unrelated, Explain: _____

b. Action taken regarding islet transplantation
- ○ Infusion not started
- ○ None
- ○ Interrupted but completed
- ○ Prematurely terminated

	No	Yes	
13.	○	○	Has the subject ever received immunosuppression and/or infection prophylaxis?

a. Relationship to immunosuppression/infection prophylaxis
- ○ Definite
- ○ Probable
- ○ Possible
- ○ Unlikely
- ○ Unrelated, Explain: _____

b. Action taken regarding immunosuppression/infection prophylaxis
- ○ None
- ○ Dose reduced
- ○ Interrupted
- ○ Discontinued
- ○ Dose increased

	No	Yes	
14.	○	○	Has the subject ever received the investigational drug, Rituximab?

a. Relationship to Rituximab
- ○ Definite
- ○ Probable
- ○ Possible
- ○ Unlikely
- ○ Unrelated, Explain: _____

b. Action taken regarding Rituximab
- ○ 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 ☐ Islet Product (check if ever received islets) ☐ Transplant Procedure (check if ever had transplant procedure initiated)	Immunosuppression and infection prophylaxis	Rituximab
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. ○ No ○ Yes ○ Doesn't apply	ii. ○ No ○ Yes ○ Doesn't apply	iii ○ No ○ Yes ○ Doesn't apply
6. Event reappeared after reintroduction?	i. ○ No ○ Yes ○ Doesn't apply	ii. ○ No ○ Yes ○ Doesn't apply	iii ○ No ○ Yes ○ Doesn't apply
7. Lot number	i.		ii.
8. Expiration Date (if known)	i. N/A		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.

STUDY TREATMENT REGIMEN

Subject ID ____ ____ -____ ____ - ____ ____ ____

A. INVESTIGATIONAL AGENT

Drug	Date	Total Dose on this Date (mg)
Rituximab	__ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)	

Add New Entry

B. INDUCTION MEDICATIONS

Drug	Date	Total Dose on this Date (mg)
O ATG O Other	__ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)	

Add New Entry

C. SUBSEQUENT TRANSPLANT MEDICATION

Drug	Date	Total Dose on this Date (mg)
O Daclizumab O Basiliximab	__ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)	

Add New Entry

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

D. MAINTENANCE IMMUNOSUPPRESSION MEDICATIONS

Add New Entry

Drug	Total Dose (mg)/Day	Start Date	Stop Date
O Sirolimus O Cyclosporine		__ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)	__ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

E. TROUGH LEVELS

Drug	Date of Draw	Trough Level (ng/mL)
O Sirolimus O Cyclosporine	__ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)	☐ Undetectable

Add New Entry

F. OTHER MAINTENANCE IMMUNOSUPPRESSION MEDICATIONS

Add New Entry

Drug	Total Dose (mg)/Day	Start Date	Stop Date
O Mycophenolate sodium O Mycophenolate mofetil O Other		__ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)	__ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)

If Other, please complete Major Protocol Deviation form.

G. INFECTION PROPHYLAXIS MEDICATIONS

Add New Entry

Drug	Total Dose/Day	Start Date	Stop Date
O TMP/SMX (SS = 1 tab)* O Clotrimazole O Valganciclovir		__ __/__ __ __/__ __ __ __ (dd/mmm/yyyy)	___/__ __ __/__ __ __ __ (dd/mmm/yyyy)

* Single Strenth TMP = 80mg; SMX = 400 mg

H. ANTICOAGULANT MEDICATIONS

Add New Entry

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

I. COMMENTS (optional)