

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.)

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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 events as determined by 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 "FCAE in Trials of Adult Pancreatic Islet Transplantation"

- Mild/Grade I
- Moderate/Grade II
- Severe/Grade III
- Life-threatening/Grade IV
- Death/Grade V

(If question 9 is Death/Grade V, go to question 10)

10. Was/will an autopsy be performed? (select one)

- No
- Yes
- Unknown

____ Please provide a de-identified copy to the DCC

11. Indicate outcome of the event

- Continuing
- Resolved (or resolved with sequelae) If resolved, give date of resolution

____/____/____

(dd/mmm/yyyy)

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No Yes12. 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 Yes13. 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 Yes14. Has the subject ever received deoxyspergualin?

a. Relationship to deoxyspergualin

- Definite
- Probable
- Possible
- Unlikely
- Unrelated, Explain:

b. Action taken regarding deoxyspergualin

- None
- Dose reduced
- Interrupted
- Discontinued
- Dose increased

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B. SUSPECT MEDICATION(S)

	Suspect Medication 1	Suspect Medication 2	Suspect Medication 3
1. Name	i. Islet Transplantation <input type="checkbox"/> Purified Human Pancreatic Islets (check if ever received islets) <input type="checkbox"/> Transplant Procedure (check if ever had transplant procedure initiated)	Immunosuppression and infection prophylaxis	Deoxyspergualin
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. <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. N/A		ii. ____/____/____ (dd/mmm/yyyy)

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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.

SAMPLE

Subject ID

A. INVESTIGATIONAL AGENT

Drug	Date	Total Dose on this Date (mg)	Add new Entry
<input type="radio"/> DSG	<input type="text"/> (dd/mmm/yyyy)	<input type="text"/>	

B. INDUCTION MEDICATIONS

Drug	Date	Total Dose on this Date (mg)	Add new Entry
<input type="radio"/> ATG	<input type="text"/>	<input type="text"/>	
<input type="radio"/> Other <input type="text"/>	(dd/mmm/yyyy)		

C. SUBSEQUENT TRANSPLANT INDUCTION MEDICATION

Drug	Date	Total Dose on this Date (mg)	Add new Entry
<input type="radio"/> Daclizumab	<input type="text"/>	<input type="text"/>	
<input type="radio"/> Basiliximab	(dd/mmm/yyyy)		

D. IMMUNOSUPPRESSIVE/ANTI-INFLAMMATORY MEDICATIONS

Drug	Date	Total Dose on this Date (mg)	Add new Entry
<input type="radio"/> Etanercept	<input type="text"/> (dd/mmm/yyyy)	<input type="text"/>	

*Sections A-D 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.*

E. MAINTENANCE IMMUNOSUPPRESSION MEDICATIONS

Drug	Total Dose (mg) / Day	Start Date	Stop Date
<input type="radio"/> Tacrolimus	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="radio"/> Sirolimus		(dd/mmm/yyyy)	(dd/mmm/yyyy)
<input type="radio"/> Cyclosporine			

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F. TROUGH LEVELS

Drug	Date of Draw	Trough Level (ng/mL)
<input type="radio"/> Tacrolimus	____/____/____ (dd/mmm/yyyy)	_____ <input type="checkbox"/> Undetectable
<input type="radio"/> Sirolimus		
<input type="radio"/> Cyclosporine		

Add new Entry

G. OTHER MAINTENANCE IMMUNOSUPPRESSION MEDICATIONS

Add new Entry

Drug	Total Dose (mg) / Day	Start Date	Stop Date
<input type="radio"/> Mycophenolate sodium	_____ (dd/mmm/yyyy)	____/____/____ (dd/mmm/yyyy)	____/____/____ (dd/mmm/yyyy)
<input type="radio"/> Mycophenolate mofetil			
<input type="radio"/> Other			

If Other, please complete Major Protocol Deviation form.**H. INFECTION PROPHYLAXIS MEDICATIONS**

Add new entry

Drug	Total Dose / Day	Start Date	Stop Date
<input type="radio"/> TMP / SMX (SS=1 tab)*	_____ (dd/mmm/yyyy)	____/____/____ (dd/mmm/yyyy)	____/____/____ (dd/mmm/yyyy)
<input type="radio"/> Clotrimazole (troche)			
<input type="radio"/> Valganciclovir (mg)			

*Single Strength TMP = 80mg SMX = 400mg

I. ANTICOAGULANT MEDICATIONS

Add new entry

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

J. COMMENTS (optional)

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