

Diabetes Prevention Trial - Type 1

TREATMENT/VISIT NON-COMPLIANCE

Complete this form if subject is unwilling or unable to comply with insulin infusion, subcutaneous insulin injections, oral medication, or scheduled visits.

Subject ID #: Subject Initials: Date: / /
F M L M M D D Y Y

Dates of Non-compliance: / / to / /
M M D D Y Y M M D D Y Y

Name of person completing form (please print): _____

1=No 2=Yes 3=Unknown	Parenteral Antigen/Experimental Treatment Subjects Only
<input type="checkbox"/>	<p>1. Subject refused insulin infusion. If "Yes": a. Indicate date insulin infusion should have been performed according to protocol: <input type="text"/><input type="text"/> / <input type="text"/><input type="text"/> / <input type="text"/><input type="text"/> M M D D Y Y b. Does subject intend to reschedule this infusion? <input type="checkbox"/> (1=No 2=Yes 3=Unknown) c. Does subject intend to comply with future infusions? <input type="checkbox"/>* (1=No 2=Yes 3=Unknown)</p>
<input type="checkbox"/>	<p>2. Subject refused subcutaneous insulin injections. a. If "Yes", does subject intend to comply with future injections? <input type="checkbox"/>* (1=No 2=Yes 3=Unknown) b. Did subject forget to take subcutaneous insulin injections? <input type="checkbox"/> (1=No 2=Yes 3=Unknown) c. Since last visit, number of injections missed <input type="text"/><input type="text"/> d. Since last visit, number of consecutive days missed <input type="text"/><input type="text"/></p>
<input type="checkbox"/>	<p>3. Subject refused to return for scheduled visits/tests. a. If "Yes", does subject intend to comply with future visits/tests? <input type="checkbox"/>* (1=No 2=Yes 3=Unknown)</p>
<p>* For Parenteral Antigen/Experimental Treatment subjects, if answers to Questions 1c, 2a, <u>AND</u> 3a are "No", complete Off-Therapy Follow-up Form (OT).</p>	

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DMU Use Only
Date rcvd: _____

1=No 2=Yes 3=Unknown	Parenteral Antigen/Closely Monitored Subjects Only
<p><input type="checkbox"/> 1. Subject refused to return for scheduled visits/tests.</p> <p style="margin-left: 20px;">a. If “Yes”, does subject intend to comply with future visits/tests? <input type="checkbox"/>* (1=No 2=Yes 3=Unknown)</p> <p style="text-align: center; margin-top: 10px;">* For Parenteral Antigen/Closely Monitored subjects, if answer to Question 1a is “No”, complete Off-Therapy Follow-up Form (OT).</p>	

1=No 2=Yes 3=Unknown	Oral Antigen Subjects Only
<p><input type="checkbox"/> 1. Subject refused oral medication.</p> <p style="margin-left: 20px;">a. If “Yes”, does subject intend to resume taking oral medication? <input type="checkbox"/>* (1=No 2=Yes 3=Unknown)</p> <p style="margin-left: 20px;">b. Did subject forget to take oral medication? <input type="checkbox"/> (1=No 2=Yes 3=Unknown)</p> <p style="margin-left: 20px;">c. Since last visit, number of doses missed <input type="text"/><input type="text"/></p> <p style="margin-left: 20px;">d. Since last visit, number of consecutive days missed <input type="text"/><input type="text"/></p> <p><input type="checkbox"/> 2. Subject refused to return for scheduled visits/tests.</p> <p style="margin-left: 20px;">a. If “Yes”, does subject intend to comply with future visits/tests? <input type="checkbox"/>* (1=No 2=Yes 3=Unknown)</p> <p style="text-align: center; margin-top: 10px;">* For Oral Antigen subjects, if answers to Questions 1a AND 2a are “No”, complete Off-Therapy Follow-up Form (OT).</p>	

All Subjects (Parenteral Antigen and Oral Antigen)	
Reason for non-compliance:	1=No 2=Yes 3=Unknown
<p>Temporary interruption in protocol <input type="checkbox"/></p> <p>Family situation <input type="checkbox"/></p> <p>Inconvenience to travel <input type="checkbox"/></p> <p>Cost/expense to subject <input type="checkbox"/></p> <p>Lacks time required of study <input type="checkbox"/></p> <p>Pregnancy <input type="checkbox"/></p> <p>Intercurrent illness <input type="checkbox"/></p> <p>Other <input type="checkbox"/></p>	<p>If yes, dates of interruption: from: <input type="text"/><input type="text"/><input type="text"/><input type="text"/>/ <input type="text"/><input type="text"/><input type="text"/><input type="text"/>/ <input type="text"/><input type="text"/><input type="text"/><input type="text"/> to: <input type="text"/><input type="text"/><input type="text"/><input type="text"/>/ <input type="text"/><input type="text"/><input type="text"/><input type="text"/>/ <input type="text"/><input type="text"/><input type="text"/><input type="text"/></p> <p>If yes, specify: _____ _____ _____</p>