

Site Number:  
Date of Visit:  
Person Completing Form:

Participant ID:  
Participant Letters:

**A. INCLUSION CRITERIA**

- |                                                                                                                          |                                                                                                                                                                                       |                         |                                |           |                      |
|--------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------------------|-----------|----------------------|
| 1. Subject is between 6 and 45 years of age (inclusive)?                                                                 | <input type="radio"/> Y                                                                                                                                                               | <input type="radio"/> N | <input type="radio"/> Not Done |           |                      |
| 2. Subject is within 3-months (100 days) of diagnosis of type 1 diabetes based on ADA criteria?                          | <input type="radio"/> Y                                                                                                                                                               | <input type="radio"/> N | <input type="radio"/> Not Done |           |                      |
| 3. Subject has at least one diabetes-related autoantibody present?                                                       | <input type="radio"/> Y                                                                                                                                                               | <input type="radio"/> N | <input type="radio"/> Not Done |           |                      |
| 4. Subject has stimulated C-peptide levels $\geq 0.2$ pmol/ml?                                                           | <input type="radio"/> Y                                                                                                                                                               | <input type="radio"/> N | <input type="radio"/> Not Done |           |                      |
| 5. Subject has not had any live immunizations in the preceding month?                                                    | <input type="radio"/> Y                                                                                                                                                               | <input type="radio"/> N | <input type="radio"/> Not Done |           |                      |
| 6. Subject is willing to forgo live vaccinations during the 12 months of treatment and for an additional 3 months?       | <input type="radio"/> Y                                                                                                                                                               | <input type="radio"/> N | <input type="radio"/> Not Done |           |                      |
| 7. Subject is willing to comply with intensive diabetes management?                                                      | <input type="radio"/> Y                                                                                                                                                               | <input type="radio"/> N | <input type="radio"/> Not Done |           |                      |
| 8. Subject weighs at least 20 kg (44 lb) at study entry?                                                                 | <input type="radio"/> Y                                                                                                                                                               | <input type="radio"/> N | <input type="radio"/> Not Done |           |                      |
| 9. Subject has signed written informed intervention consent for participation                                            | <input type="radio"/> Y                                                                                                                                                               | <input type="radio"/> N | <input type="radio"/> Not Done |           |                      |
| If yes, date consent was obtained:                                                                                       | <table border="0" style="margin-left: 20px;"> <tr> <td style="text-align: center;">_ / _ / _</td> </tr> <tr> <td style="text-align: center;">DAY    MONTH    YEAR</td> </tr> </table> |                         |                                | _ / _ / _ | DAY    MONTH    YEAR |
| _ / _ / _                                                                                                                |                                                                                                                                                                                       |                         |                                |           |                      |
| DAY    MONTH    YEAR                                                                                                     |                                                                                                                                                                                       |                         |                                |           |                      |
| If yes, was permission given for samples of the participant's blood to be stored for other tests?                        | <input type="radio"/> Y                                                                                                                                                               | <input type="radio"/> N | <input type="radio"/> Not Done |           |                      |
| If yes: <input type="checkbox"/> with DNA <input type="checkbox"/> without DNA (this answer will not affect eligibility) |                                                                                                                                                                                       |                         |                                |           |                      |

**B. EXCLUSION CRITERIA**

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|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|-------------------------|--------------------------------|
| 1. Subject is immunodeficient or has clinically significant chronic lymphopenia?                                                                                                                                                                                                                                                     | <input type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> Not Done |
| 2. Subject has an active infection?                                                                                                                                                                                                                                                                                                  | <input type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> Not Done |
| 3. Subject has a positive PPD test result?                                                                                                                                                                                                                                                                                           | <input type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> Not Done |
| 4. Subject is currently using medications known to influence glucose tolerance?                                                                                                                                                                                                                                                      | <input type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> Not Done |
| 5. Subject requires use of other immunosuppressive agents?                                                                                                                                                                                                                                                                           | <input type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> Not Done |
| 6. Subject has serologic evidence of current or past HIV, Hepatitis B or C infection?                                                                                                                                                                                                                                                | <input type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> Not Done |
| 7. Subject has complicating medical issues or abnormal clinical laboratory results that in the opinion of the investigator would interfere with study conduct or cause increased risk (including pre-existing cardiac disease, COPD, neurological or blood count abnormalities such as lymphopenia, leucopenia or thrombocytopenia)? | <input type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> Not Done |
| 8. Subject has a history of malignancies?                                                                                                                                                                                                                                                                                            | <input type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> Not Done |
| 9. Subject is currently using non-insulin pharmaceuticals to affect glycemic control?                                                                                                                                                                                                                                                | <input type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> Not Done |
| 10. Subject is currently participating in another type 1 diabetes treatment study?                                                                                                                                                                                                                                                   | <input type="radio"/> Y | <input type="radio"/> N | <input type="radio"/> Not Done |

*If FEMALE, answer the following questions (11-17):*

