

Site Number: _____ Screening ID: _____ - ____ Participant Letters: _____

The Study Coordinator should complete this form for every change in participant's study status (inactivation or reactivation). Inactive status is declared when a participant is unwilling, or unable to continue making future follow-up visits. Note: Development of 2 persistent positive autoantibodies or T1D is considered inactivation for purposes of this study.

A. REPORT INFORMATION

Status Identification Number: **####**

1. Date of report (e.g. 05/Sep/2006):

____/____/____
DAY MONTH YEAR

2. Last attended study visit before change in status (check one):

- | | | | |
|------------------------------------------------------------------|--------------------------------------------------------------------------------------|-------------------------------------------|--------------------------------------------------------|
| <input type="checkbox"/> 91 Pregnant Woman Screening/ Enrollment | <input type="checkbox"/> 95 Entry A Infant Screening combined with Infant Enrollment | <input type="checkbox"/> 3 3 Months old | <input type="checkbox"/> 24 24 Months old |
| <input type="checkbox"/> 92 Delivery | <input type="checkbox"/> 93 Infant Enrollment combined with 3 Months Old | <input type="checkbox"/> 6 6 Months old | <input type="checkbox"/> 30 30 Months old |
| <input type="checkbox"/> 1 Infant Screening | <input type="checkbox"/> 94 Infant Enrollment combined with 6 Months Old | <input type="checkbox"/> 9 9 Months old | <input type="checkbox"/> 36 36 Months old |
| <input type="checkbox"/> 2 Infant Enrollment | <input type="checkbox"/> 96 Non-Qualified Debriefing Visit | <input type="checkbox"/> 12 12 Months old | <input type="checkbox"/> 42 42 Months old |
| | | <input type="checkbox"/> 15 15 Months old | <input type="checkbox"/> 48 48 Months old |
| | | <input type="checkbox"/> 18 18 Months old | <input type="checkbox"/> 99 Other, Specify date: _____ |
| | | <input type="checkbox"/> 21 21 Months old | |

B. STATUS CHANGE INFORMATION – ACTIVATION / INACTIVATION

1. Effective date for change in status:

(For inactivation, record date of last contact with participant)

____/____/____
DAY MONTH YEAR

2. Change in status that has occurred (check one):

- | | |
|-----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> 1 Change to active status following period of inactivity | <input type="checkbox"/> 2 Change to inactive status following period of active study participation |
|-----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|

C. DESCRIPTION OF INACTIVATION

1. Record the primary reason for participant inactivation (check one):

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|
| <input type="checkbox"/> 1 a. Infant HLA typing does NOT meet study criteria | <input type="checkbox"/> 6 f. Development of 2 persistent autoantibodies |
| <input type="checkbox"/> 2 b. Adverse event* (check all that apply)
1) <input type="checkbox"/> 1 Mom 2) <input type="checkbox"/> 1 Infant | <input type="checkbox"/> 7 g. Development of T1D** |
| <input type="checkbox"/> 3 c. Moving out of the area and cannot be followed | <input type="checkbox"/> 8 h. End of study |
| <input type="checkbox"/> 4 d. Withdrew consent,
1) Explain: _____ | <input type="checkbox"/> 9 i. Other,
1) Specify: _____ |

5 e. Lost to follow-up (e.g. unable to contact)

2. Is the participant still willing to be contacted?

Y N

* Complete an Adverse Event Report Form (NPP23) as required.
** Complete the Type 1 Diabetes Onset Form (NPP24).

Initials (first, middle, last) of person completing this form: _____
F M L

Date form completed: ____/____/____
DAY MONTH YEAR

On all questions write “?” if the desired information is currently unavailable, but is being checked and will be known in future updates. Write “*” if the desired information is permanently unavailable (i.e. will not be known in any future updates).