CTLA-4 Ig Study
CHANGE OF STATUS FORM

Type 1 Diabetes TrialNet

Form CTL15
01 JAN 2008
Version 1.0
Page 1 of 1

Site Number: __ __ __ __   Screening ID: __ __ __ __ __ - __   Participant Letters: __ __ __

Complete this form for two circumstances:
    (1) An active participant withdraws or
    (2) A participant who was withdrawn decides to become reactivated in the study
Withdrawn status is declared when a participant is unwilling, or unable, to continue making future follow-up visits. Complete this form for every change of status that occurs. For example, if a participant becomes withdrawn and then reactivates at a later date, two separate forms should be completed.

A. REPORT INFORMATION

Status Identification Number: # # # #

1. Date of report: __ __ / __ __ __ / __ __ __ __
       DAY   MONTH   YEAR

2. Last attended study visit *before* change in status?

☐ 0 Baseline	☐ 8 Visit 8	☐ 16 Visit 16	☐ 24 Visit 24
☐ 1 Visit 1	☐ 9 Visit 9	☐ 17 Visit 17	☐ 25 Visit 25
☐ 2 Visit 2	☐ 10 Visit 10	☐ 18 Visit 18	☐ 26 Visit 26
☐ 3 Visit 3	☐ 11 Visit 11	☐ 19 Visit 19	☐ 27 Visit 27
☐ 4 Visit 4	☐ 12 Visit 12	☐ 20 Visit 20	☐ 28 Visit 28
☐ 5 Visit 5	☐ 13 Visit 13	☐ 21 Visit 21	☐ 29 Visit 29
☐ 6 Visit 6	☐ 14 Visit 14	☐ 22 Visit 22	☐ 30 Visit 30
☐ 7 Visit 7	☐ 15 Visit 15	☐ 23 Visit 23	☐ 31 Visit 31

B. STATUS CHANGE INFORMATION

1. Date change in status became effective: __ __ / __ __ __ / __ __ __ __
       DAY   MONTH   YEAR

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

    ☐ 1   An active participant withdraws (proceed to **Section C**)

    ☐ 2   A participant who was withdrawn decides to become reactivated in the study (proceed to **Section D**)

C. PARTICIPANT WITHDRAWING FROM THE STUDY

1. Date of withdrawal: __ __ / __ __ __ / __ __ __ __
       DAY   MONTH   YEAR

2. Record the primary reason for withdrawal *(check one)*:

    ☐ 1 Adverse event[1]   ☐ 3 Pregnancy[1,3]   ☐ 5 Lost to follow-up   ☐ 99 Other
    ☐ 2 Death[1,2]   ☐ 4 Withdrawn consent   ☐ 6 Ineligible

    a. If OTHER, specify: _____

3. Is the subject still willing to be contacted?   Y   N

[1]*An Adverse Event Report Form (**CTL13**) **must** be completed.* [2]*A Mortality Event Form (**CTL13M**) **must** be completed.* [3]*A Pregnancy Confirmation Form (**CTL14**) **must** be completed. This is a temporary change in status if the woman agrees to continue in the study after delivery.*

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).*

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D. REACTIVATION OF PREVIOUSLY WITHDRAWN PARTICIPANT

1. Date of reactivation: __ __ / __ __ __ / __ __ __ __
                                                              DAY   MONTH   YEAR

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

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

Signature of Principal Investigator: _____

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).*