

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(2) A participant who was withdrawn decides to become reactivated in the study

Withdrawn status is declared when a participant is unwilling, or unable, to continue making future follow-up visits.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 For example, if a participant becomes withdrawn and then reactivates at a later date, two separate forms should be completed.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?

<input type="checkbox"/> 0 Baseline	<input type="checkbox"/> 8 Visit 8	<input type="checkbox"/> 16 Visit 16	<input type="checkbox"/> 24 Visit 24
<input type="checkbox"/> 1 Visit 1	<input type="checkbox"/> 9 Visit 9	<input type="checkbox"/> 17 Visit 17	<input type="checkbox"/> 25 Visit 25
<input type="checkbox"/> 2 Visit 2	<input type="checkbox"/> 10 Visit 10	<input type="checkbox"/> 18 Visit 18	<input type="checkbox"/> 26 Visit 26
<input type="checkbox"/> 3 Visit 3	<input type="checkbox"/> 11 Visit 11	<input type="checkbox"/> 19 Visit 19	<input type="checkbox"/> 27 Visit 27
<input type="checkbox"/> 4 Visit 4	<input type="checkbox"/> 12 Visit 12	<input type="checkbox"/> 20 Visit 20	<input type="checkbox"/> 28 Visit 28
<input type="checkbox"/> 5 Visit 5	<input type="checkbox"/> 13 Visit 13	<input type="checkbox"/> 21 Visit 21	<input type="checkbox"/> 29 Visit 29
<input type="checkbox"/> 6 Visit 6	<input type="checkbox"/> 14 Visit 14	<input type="checkbox"/> 22 Visit 22	<input type="checkbox"/> 30 Visit 30
<input type="checkbox"/> 7 Visit 7	<input type="checkbox"/> 15 Visit 15	<input type="checkbox"/> 23 Visit 23	<input type="checkbox"/> 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☐ 2 A participant who was withdrawn decides to become reactivated in the study (proceed to **Section D**)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 event¹

☐ 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☐ 4 Withdrawn consent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

¹An Adverse Event Report Form (CTL13) **must** be completed. ²A Mortality Event Form (CTL13M) **must** be completed. ³A 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).



CTLA-4 Ig Study
CHANGE OF STATUS FORM

Form CTL15

01 JAN 2008

Version 1.0

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Site Number: _____

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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).*