

Site Number: _____ Screening ID: _____ - ____ First 3 Letters of First Name: _____

Complete this form if a participant changes study status. This form should be completed for two circumstances:

- (1) An active participant becomes inactive for some previously unforeseen reason
- (2) A participant who is inactive decides to become reactivated in the study

Inactive status is declared when a participant is unwilling, or unable, to continue making future follow-up visits. This form should be completed for every change of status that occurs, even if the participant is the same. Therefore, if a participant becomes inactive and then reactivates at a later date, two separate forms should be completed.

A. REPORT INFORMATION

1. Date of report:

____ / ____ / ____
MM DD YYYY

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

- | | | | |
|-------------------------------------|-------------------------------------|--------------------------------------|--------------------------------------|
| <input type="checkbox"/> 2 Baseline | <input type="checkbox"/> 6 Week 4 | <input type="checkbox"/> 14 Month 9 | <input type="checkbox"/> 26 Month 21 |
| <input type="checkbox"/> 3 Week 1 | <input type="checkbox"/> 7 Month 2 | <input type="checkbox"/> 17 Month 12 | <input type="checkbox"/> 29 Month 24 |
| <input type="checkbox"/> 4 Week 2 | <input type="checkbox"/> 8 Month 3 | <input type="checkbox"/> 20 Month 15 | |
| <input type="checkbox"/> 5 Week 3 | <input type="checkbox"/> 11 Month 6 | <input type="checkbox"/> 23 Month 18 | |

B. STATUS CHANGE INFORMATION

1. Date change in status became effective:

____ / ____ / ____
MM DD YYYY

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

- 1 Changing to active status following period of inactivity
- 2 Changing to inactive status following period of active study participation

IF INACTIVE,

a. Is the subject willing and able to be contacted during the inactive period?

Y N

b. Indicate reason for change in status: (*check one*):

- | | | | |
|---|---|--|----------------------------------|
| <input type="checkbox"/> 1 Adverse event ¹ | <input type="checkbox"/> 3 Pregnancy ^{1,3} | <input type="checkbox"/> 5 Lost to follow-up | <input type="checkbox"/> 9 Other |
| <input type="checkbox"/> 2 Death ^{1,2} | <input type="checkbox"/> 4 Withdrawn consent | <input type="checkbox"/> 6 Ineligible | |

1. IF OTHER, specify: _____

¹ An Adverse Event Report Form (MMF07) must be completed.

² A Mortality Event Form (MMF07M) must be completed.

³ A Pregnancy Confirmation Form (MMF09) must be completed. This is a temporary change in status if the woman agrees to continue in the study after delivery.

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

Date form completed: ____ / ____ / ____
MM DD YYYY

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).