

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?

☐ ₂ Baseline

☐ ₆ Week 4

☐ ₁₄ Month 9

☐ ₂₆ Month 21

☐ ₃ Week 1

☐ ₇ Month 2

☐ ₁₇ Month 12

☐ ₂₉ Month 24

☐ ₄ Week 2

☐ ₈ Month 3

☐ ₂₀ Month 15

☐ ₅ Week 3

☐ ₁₁ Month 6

☐ 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*):

☐ ₁ Adverse event¹

☐ ₃ Pregnancy^{1,3}

☐ ₅ Lost to follow-up

☐ ₉ Other

☐ ₂ Death^{1,2}

☐ ₄ Withdrawn consent

☐ 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).