

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

<input type="checkbox"/> <sub>1</sub> Changing to active status following period of inactivity	<input type="checkbox"/> <sub>2</sub> Changing to inactive status following period of active study participation
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**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"/> <sub>1</sub> Adverse event <sup>1</sup> | <input type="checkbox"/> <sub>3</sub> Pregnancy <sup>1,3</sup> | <input type="checkbox"/> <sub>5</sub> Lost to follow-up | <input type="checkbox"/> <sub>9</sub> Other |
| <input type="checkbox"/> <sub>2</sub> Death <sup>1,2</sup>       | <input type="checkbox"/> <sub>4</sub> Withdrawn consent        | <input type="checkbox"/> <sub>6</sub> Ineligible        |   |

1. IF OTHER, specify: \_\_\_\_\_

<sup>1</sup> An Adverse Event Report Form (MMF07) **must** be completed.  
<sup>2</sup> A Mortality Event Form (MMF07M) **must** be completed.  
<sup>3</sup> 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).*