

Site Number:  
Date of Visit:  
Person Completing Form:

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- (2) A participant who was withdrawn decides to become reactivated in the study

Withdrawn status is declared when a participant is unwilling, or unable, to continue making future follow-up visits.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 For example, if a participant becomes withdrawn and then reactivates at a later date, two separate forms should be completed.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

1. Date change in status became effective:

\_\_\_/\_\_\_/\_\_\_  
DAY MONTH YEAR

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

- ☐ An active participant withdraws (proceed to **Section B**)
- ☐ A participant who was withdrawn decides to become reactivated in the study (proceed to **Section C**)

### B. PARTICIPANT WITHDRAWING FROM THE STUDY

1. Date of withdrawal:

\_\_\_/\_\_\_/\_\_\_  
DAY MONTH YEAR

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

- ☐ Adverse event<sup>1</sup> ☐ Pregnancy<sup>1,3</sup> ☐ Lost to follow-up ☐ Other
- ☐ Death<sup>1,2</sup> ☐ Withdrawn consent ☐ Ineligible

a. If OTHER, specify:

\_\_\_\_\_

3. Is the participant still willing to be contacted?

☐ Yes ☐ No ☐ Unknown

<sup>1</sup>An Adverse Event Report Form **must** be completed. <sup>2</sup>A Mortality Event Form **must** be completed. <sup>3</sup>A Pregnancy Confirmation Form **must** be completed. This is a temporary change in status if the woman agrees to continue in the study after delivery.

### C. REACTIVATION OF PREVIOUSLY WITHDRAWN PARTICIPANT

1. Date of reactivation:

\_\_\_/\_\_\_/\_\_\_  
DAY MONTH YEAR