Site Number: Date of Visit: Person Completing Form:

Type

**Diabetes** 

TrialNet

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(2) A participant who was withdrawn decides to become reactivated in the study

Withdrawn status is declared when a participant is unwilling, or unable, to continue making future follow-up visits.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 For example, if a participant becomes withdrawn and then reactivates at a later date, two separate forms should be completed.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

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

1. Date change in status became effective:

- Ο 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  - A participant who was withdrawn decides to become reactivated in the study (proceed to Section C)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:							/ 	YEAR	
2. Record the primary reason for withdrawal (select one):									
	0	Adverse event <sup>1</sup>	0	Pregnancy <sup>1, 3</sup>	0	Lost to follow-up	0	Other	
	0	Death <sup>1, 2</sup>	0	Withdrawn consent	0	Ineligible			
a. If OTHER, specify:									
3. Is the participant still willing to be contacted?					O Yes	O No O Unknown			
<sup>1</sup> An Adverse Event Report Form <b>must</b> be completed. <sup>2</sup> A Mortality Event Form <b>must</b> be completed. <sup>3</sup> A Pregnancy Confirmation									
Form <b>must</b> 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## C. REACTIVATION OF PREVIOUSLY WITHDRAWN PARTICIPANT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:

Ο

YEAR DAY MONTH

MONTH

YFAR

DAY

Change of S	5
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